

# INTERSTATE TRANSPORTATION OF HUMAN PATHOGENS

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104-834

## HEARING

BEFORE THE

## COMMITTEE ON THE JUDICIARY UNITED STATES SENATE

ONE HUNDRED FOURTH CONGRESS

SECOND SESSION

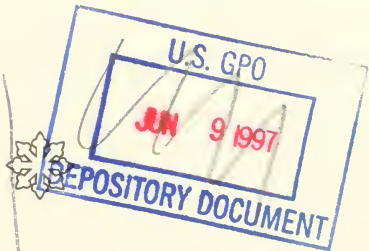
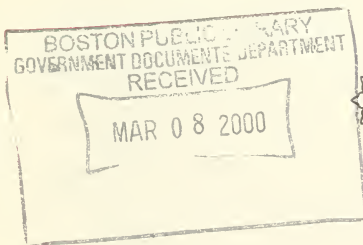
ON

EXAMINING ISSUES RELATING TO THE INTERSTATE TRANSPORTATION  
OF HUMAN PATHOGENS

MARCH 6, 1996

Serial No. J-104-67

Printed for the use of the Committee on the Judiciary



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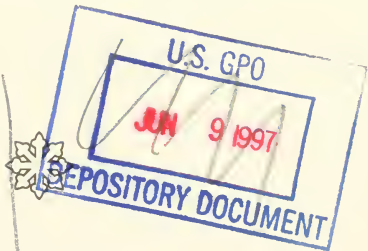
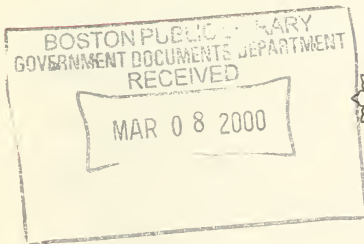
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# INTERSTATE TRANSPORTATION OF HUMAN PATHOGENS

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WEDNESDAY, MARCH 6, 1996

U.S. SENATE,  
COMMITTEE ON THE JUDICIARY,  
*Washington, DC.*

The committee met, pursuant to notice, at 10:08 a.m., in room SD-226, Dirksen Senate Office Building, Hon. Orrin G. Hatch (chairman of the committee) presiding.

Also present: Senators Thurmond, Specter, DeWine, and Feinstein.

## OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM THE STATE OF UTAH

The CHAIRMAN. I apologize for being just a little bit late. It is just one of those things that you can't get away from the office.

This morning, the Judiciary Committee will examine concerns arising from the interstate transportation of human pathogens. It may surprise the American people to know that very dangerous, indeed deadly organisms which cause diseases and death in human beings are available for purchase across State lines not only by those with a legitimate use for them, but by anyone else. These organisms include the agents that cause the bubonic plague, anthrax, and other diseases. In fact, the Federal Government has more strict regulations on the interstate transportation of pathogens causing disease in plants and animals than it has for the interstate transportation of agents that cause disease in humans.

I favor regulatory reform and a reduction in the Government's overall regulatory burden on the American people, but that is not to say, of course, that the Federal Government has no legitimate role to play. Some of the biological agents we will discuss today may be usable as weapons of mass destruction by domestic terrorists and, of course, access to them should be regulated.

A recent Washington Post story reported that in May 1995, an individual in Ohio faxed an order for three vials of the agent that causes the plague from the American Type Culture Collection, the ATCC, in Maryland. The purchaser's letterhead appeared to be that of a laboratory. For instance, I might say for those of you who are not familiar with the bubonic plague, this disease, otherwise known as the black death, killed one-third of the people in 14th century Europe.

When the purchaser called ATCC to complain about slow delivery, the sales representative became concerned about whether the caller was someone who should have the plague agent. A series of

telephone calls followed which led police, Ohio public officials, the FBI, and emergency workers to scour the purchaser's home. In the home, they found nearly a dozen M-1 rifles, smoke grenades, blasting caps, and white separatist literature. The deadly microorganisms were found in the glove compartment of the purchaser's automobile still packed as shipped.

The purchaser was prosecuted under the wire and mail fraud statutes, and even these charges would not have been possible if the purchaser had not sent a false statement on the letterhead of a nonexistent laboratory stating that the laboratory assumed responsibility for the shipment, as the seller had required.

There are Federal regulations both with regard to the management of pathogenic agents, such as how they must be packaged and stored, and on the protection of clinical and research laboratory workers. The only restrictions on how a person may receive human pathogens across State lines, however, are imposed by the sellers of the pathogens themselves. Human pathogenic agents should be legitimately available to governmental and private clinical and research laboratories to conduct research and support care for sick patients. These agents should not be available to just anyone who wants them as they now are.

Now, I want to work with the Federal agencies, those who have a legitimate need to obtain these pathogens, and my colleagues in finding a sensible way. Together, we may be able to keep human pathogens out of the wrong hands. Strategies to decrease the chances of criminal misuse of human pathogens must take into account that these agents are purchased, transported, and possessed by many government agencies, companies, and individuals for legitimate use. But human pathogens are too readily available today, as the Ohio episode demonstrates, and some action is warranted.

Now, we are going to hear first from Congressman Ed Markey. We are real happy to have you here, Ed. We appreciate you taking time to come over to this side of the Capitol and we look forward to your testimony.

If Joseph Kennedy can arrive, we will have him, and then hopefully Congressman John Kasich. If they can't make it, we are going to have Congressman Markey handle it for all of them. They have all taken a leading role on this issue in the House, and I might say that John Kasich wanted to be with us, but cannot, and he has submitted a statement for the record, and we will accept statements from others as well.

[The prepared statement of Mr. Kasich follows:]

PREPARED STATEMENT OF HON. JOHN R. KASICH, A REPRESENTATIVE IN CONGRESS  
FROM THE STATE OF OHIO

Thank you very much for this opportunity to testify on an issue about which I feel very strongly. This country has serious gaps in its legal safeguards against the misuse or terrorist employment of biological warfare agents. In Congressional testimony after the Persian Gulf War, former Chairman of the Joint Chiefs of Staff Colin Powell stated, " \* \* \* of all the various weapons of mass destruction, biological weapons are of the greatest concern to me." He had good reason to be concerned.

According to an unclassified CIA study, biological agents are inherently more toxic than chemical nerve agents on a weight-for-weight basis. Moreover, they are potentially more effective because most are naturally occurring pathogens, and are self replicating—which means they could be spread far beyond the attack site by contagion. The CIA further says that there are no reliable biological warfare detection devices currently available. The principal deterrent to their use in organized war-

fare has been uncertainty about their ultimate consequences, including the risk of accidentally exposing friendly forces. But that kind of deterrent is of course far less likely to be a consideration for a terrorist group. We simply have to assume that the more horrible and cruel the weapon, the greater the attractiveness to a certain type of deranged mentality.

The difficulty in regulating biological agents is hard to underestimate. There is very little that would distinguish a vaccine plant from a biological weapons production facility. For example, known biological warfare threat agents include the organisms that cause anthrax, botulism, and plague; yet there is also extensive legitimate research that requires the production of these agents, for instance, for vaccine production. That is why it is crucial that we carefully regulate the legitimate scientific use of these materials as the first "firewall" against misuse. The second "firewall" is to increase the punishment provided by law for the unauthorized use of these agents, for instance, the obtaining of biological agents under false pretenses. I think everyone in this room would agree that anyone who obtains plague or anthrax or botulin cultures through deception ought to be subject to stiffer penalties than simple mail fraud. Yet, incredibly, that is the case today, and it is one of the reasons I am so concerned about this subject.

In Lancaster, Ohio, not far from my congressional district, an unauthorized person, Larry Wayne Harris, obtained a sample of bubonic plague culture by simply writing to the American Type Culture Collection on a phony letterhead. It was probably only because the sample was delayed in the mail that law enforcement became aware that an unauthorized person had compromised the security of the system. The delay caused Harris to call the institute and ask why the culture he ordered hadn't arrived. Only then did an institute employee become suspicious that Harris was not a qualified recipient, and called the police. Law enforcement authorities found the bubonic plague samples in the glove compartment of Harris's car.

It so happens that Harris was a member of Aryan Nation. But what he did was no crime, beyond the issue of wire fraud and mail fraud. Edmund Sargus, the U.S. Attorney for the Southern District of Ohio, said that the law currently treats the improper disposal of motor oil by a service station more severely than what Harris did.

That is why I believe it is absolutely necessary to close the legal loopholes that have allowed biological agents to be treated so leniently. We cannot tolerate even one case in which biological weapons are used. Last year's tragedy of the Japanese "Doomsday Cult," which used a weapon of mass destruction (sarin nerve gas) in the Tokyo subway, shows that a previously unknown group can cause massive casualties. I understand that none of our intelligence agencies had any information on the group. We simply cannot rely solely on an intelligence warning to prevent future incidents in the United States. It is vital that we begin to change the law to reflect the new reality of weapons of mass destruction in the hands of terrorists. I am delighted to work with my colleagues, Ed Markey and Joe Kennedy, on a bipartisan basis and begin to solve its problem. Thank you.

The CHAIRMAN. We will then have a panel from the Justice Department and the Centers for Disease Control and Prevention. Our last panel will include Dr. David Sundwall, of the American Clinical Laboratory Association; Dr. Kenneth Berns, who is the president of the American College of Microbiology; and Dr. Barth Reller, representing the American Type Culture Collection. So we welcome you all here this morning.

We will begin with you, Representative Markey. Thanks for coming. We appreciate your being here and we look forward to your testimony.

#### STATEMENT OF HON. EDWARD J. MARKEY, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MASSACHUSETTS

Representative MARKEY. Thank you, Senator, very much, and I very much appreciate the invitation to testify before you this morning. Congressmen Kennedy and Kasich and I are introducing complementary legislation, one dealing with the criminalization of the transfer and use of these materials, the other ensuring that the CDC does go into a rulemaking that will ensure that we have per-

manent controls placed upon the management and reuse of any of these materials.

You know, in 1900, the average male and female in the United States died at age 48; that is, we had gone all the way from the Garden of Eden to 1900 and the life expectancy of the average male and female was still 48 years of age. Today, the life expectancy is 79 years of age. In other words, we have added 31 years to the life expectancy of human beings in only this century, and we extended this across the entire planet as an ethic.

Now, why is that the case? Well, there are a lot of reasons, but at the heart of it was the research which was done, much of it—most of it, in fact, sponsored by the Federal Government, to isolate the infectious diseases that had rumbled through societies, countries, families, for centuries on end. The isolation and eradication or limitation of these diseases is to a very large extent the story of the 20th century.

We do still have diseases which we have not, in fact, cured or isolated. Amongst those are the Ebola and others which you have mentioned, Mr. Chairman. Those diseases in the wrong hands would have the potential of wrecking havoc at a level that we have not seen in our country in a very long time. That white supremacist from Ohio, Larry Wayne Harris, last year who gained access to very potentially dangerous, infectious substance, and the Aum group in Japan, an Armageddon group which gained access to sarin gas, which they were able to use to terrorize the whole city of Tokyo, are good examples of what happens.

I think we are all surprised that better controls haven't been placed upon the transfer of the materials which are kept and isolated. The fact that there are not formalized controls, I think, is a shock to all of us. Now, I know that the CDC, the Justice Department, and HHS have been working now on this issue since last summer, but I do believe quite firmly that we should just pass a law to ensure that, permanently, there will be a control regime which is placed over these materials. Notwithstanding the good work which the CDC is doing right now, I think it is absolutely critical for us to pass that legislation.

So I thank you for the invitation to testify here today. I think it is something that we should all be very concerned about. In the wrong hands, it could cause devastating consequences for large portions of our population.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Congressman Markey. You have set the stage really well and I appreciate it. One of your constituents up there in Boston, Robin Cook, just wrote this bestseller, called "Contagion," which points this out in a very practical way. I think it is the kind of a book that everybody ought to read because although his books are fiction, they really are more truth than fiction in a very real sense with regard to some of these matters, and especially in this case of human pathogens.

[The prepared statement of Mr. Markey follows:]

#### PREPARED STATEMENT OF REPRESENTATIVE EDWARD J. MARKEY

Mr. Chairman, I want to commend you on calling this morning's hearing. Surely, the importance of keeping infectious agents that could pose a serious threat to the

public's health and safety out of the hands of dangerous people is something we can all agree on, even in these often partisan times.

We all know the story of Larry Wayne Harris, the Ohio white supremacist who ordered bubonic plague through the mail last summer. It's frightening to think that just about anybody with a 32 cent stamp and a little chutzpah could get a hold of any number of potentially dangerous infectious substances. The Ohio case may be an isolated incident or it may not be—we really don't know. Why? Because the federal government has no system in place today to regulate the transfer of these agents within the United States. I think that's a situation that needs to be corrected, and I am introducing legislation today to do so.

Why worry about the flow of potentially dangerous infectious agents within our borders? Let me read you a few lines from an article on the threat posed by these agents when they are converted into biological weapons, written by U.S. Navy Commander Stephen Rose for the Naval War College Review. Cmdr. Rose writes that:

Science can now reshuffle the genetic deck of micro-organisms to produce a theoretically unlimited number of combinations, each with its own unique blend of toxicity, hardiness, incubation period, etc. In short, it is becoming possible to synthesize biological agents to military specifications. Thus, the world lies on the threshold of a dangerous era of designer bugs as well as designer drugs.

Biological weapons have been called the "poor man's atomic bomb." They are relatively cheap to produce, and you get an appallingly big "bang for your buck." In fact, experts report that some of the supertoxins that have been developed in recent years are ten thousand times more potent than the nerve gases we are more accustomed to, which have been described as "mere perfume" in comparison to some of their biological competitors. The Office of Technology Assessment reports that some 15 nations, including Libya, North Korea, and Iraq, are suspected of having biological weapons development programs.

Clearly, the potential of biological weapons to rain devastation down upon their victims should give those charged with preventing international terrorist attacks on our nation cause for serious concern. However, the lesson we learned from the tragedy at Oklahoma City is that we cannot be satisfied to only look outward for terrorist threats. We must also be vigilant against "home-grown" threats from paramilitary groups within our borders, which could use biological weapons against their fellow Americans to further their anti-government agendas.

On the morning of March 20, 1995, the Japanese government was faced with just such a situation. A "home-grown" Armageddon-group called Aum Shinrikyo released sarin gas—a deadly nerve agent that is 500 times more toxic than cyanide gas—in the Tokyo subway system, killing twelve people and injuring thousands more. According to a staff report on the incident prepared by the Senate Permanent Subcommittee on Investigations, the Aum sect had its own chemical weapons manufacturing plant (for the production of sarin gas) and was trying to develop biological weapons, including botulism and anthrax. To get a sense of power of those weapons, consider this: 3 billionths of an ounce of botulism toxin would be enough to kill me.

Incidentally, the staff report concluded that the Aum sect was "a clear danger to not only the Japanese government but also to the security interests of the United States," which was the target of much of the Aum leader's rhetoric.

In an effort to reduce the risk of a similar attack in the United States, I have introduced legislation directing the Centers for Disease Control to develop a regulatory regime to control access to those infectious agents that could pose the greatest threat to public health if they fell into the wrong hands. It is my understanding that a working group including representatives of CDC, the Department of Justice, and other relevant federal agencies already has begun to develop such a regime. My bill would ensure that that work is completed and the system is in place within one year of its enactment.

I am hopeful that this legislation will be given the swift attention that the issue it addresses demands in the House, and that the Senate will take up similar legislation soon. I also hope the administration will respond promptly to the request that I recently made with Senator Specter and a number of other House and Senate members for the transfer of approximately \$7 million from the Defense Department to the Office of Emergency Preparedness at the Department of Health and Human Services. This transfer would ensure that the office, which has been charged with coordinating emergency response in the event that a biological weapon is ever used on American soil, has the necessary resources to accomplish this critical mission. The administration requested additional funds for this office from the Appropriations Committees last July, but that request was not approved. It is my understand-

ing that, under this approach, additional funds could be provided for OEP without further congressional action.

Thank you, again, for holding today's hearing and allowing me to participate in it.

The CHAIRMAN. Joe Kennedy, we are happy to welcome you here. We are glad to have you on our side of the Capitol and look forward to taking your testimony at this time.

# **STATEMENT OF HON. JOSEPH P. KENNEDY, II, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF MASSACHUSETTS**

Representative KENNEDY. Thank you very much, Mr. Chairman. I, first of all, want to thank you very much for the keen interest and awareness that you have shown on this issue. Obviously, I think your State perhaps more than any other in the country has had experiences in its history with chemical and biological agents that have caused harm and destruction, and probably has an acute awareness of the downside of some of the unbelievable toxins that have been both created by man and created by God and the destructive nature that can be utilized if they fall into the wrong hands.

So I appreciate your willingness and the other members' willingness to delve into this issue, and I think it is an issue that, as I am sure my friend, Ed Markey, has indicated, requires, I think, a couple of different approaches if we are going to be successful in dealing with the harm that potentially can affect the American people.

I actually think that the approach that Mr. Markey is taking, to begin with, makes a great deal of sense. It is my feeling that at a certain point the Government does have to protect its citizens, and there are times when that is going to require additional regulation and fact that we do not currently have regulations and rules about who can go out and actually create these unbelievable toxins is absolutely astounding.

We regulate and tell people that they can't go out and build a nuclear bomb in America, but when it comes down to coming up with a chemical or biological weapon that, in fact, could kill many more people than a nuclear bomb can, we don't have a single regulation. So I think Mr. Markey's approach in saying that we ought to have a broad and all-encompassing set of rules and regulations trying to determine who ought to have access and who ought to be licensed to, in fact, go out and participate in these activities just absolutely makes sense.

There is a second, and I think more immediate set of concerns that both Mr. Kasich and I in the House—and I understand that in the Senate you might be introducing legislation soon, if you already haven't, Mr. Chairman, that I think can deal with some of the sort of gross holes in the law that exist at the moment.

Specifically, Mr. Kasich and I would amend the criminal statute to impose mandatory penalties, which at the moment simply don't exist, first, against anyone who knowingly develops, produces, stockpiles, transfers, acquires, or attempts to acquire under false pretenses any biological agent, toxin or delivery system for use as weapons, or knowingly assists a foreign state or any organization to deliver a weapon of mass destruction intended to kill, injure, or

otherwise harm any living human being in the United States; and, second, against anyone who knowingly attempts, conspires or threatens to use any biological agent, toxin or delivery system for use as a weapon, or knowingly assists a foreign state or any organization to do so.

The legislation would also add the term "recombinant DNA material" to the definitions of what constitutes a potential biological weapon if used improperly or as a weapon of mass destruction. Finally, the legislation would expand the current definition of what constitutes a criminal offense to include those threaten to use a biological weapon to kill or injure another.

This gap in current law was evident last year on Good Friday when, in the weeks following the terrorist incidents in Japan involving the toxic sarin, an anonymous threat was lodged against Disneyland and thousands of visitors. The threat demanded a ransom note to be paid or a toxic substance would be released at Disneyland amusement park. Fortunately, the incident did not result in the threat being carried out, but clearly there is a need to address these cases where such threats or other acts of extortion might occur.

In summary, there are two important issues facing the committee in considering biological and chemical weapons legislation. The first issue is how we can best limit access to biological organisms that can be used by a domestic terrorist to make a weapon of mass destruction without inhibiting the very legitimate research of the scientific community in this area. The other issue is how to best and swiftly address the concerns of the glaring gaps in the current weapons of mass destruction Federal law.

The legislation that I have developed, the Kennedy-Kasich-Markey legislation, addresses issues involving the criminal code within the jurisdiction of this committee. The FBI and the CIA have both testified before the Congress that terrorism in the form of biological and chemical weapons is the greatest law enforcement challenge in the next decade. The bill responds to several incidents in Ohio, Minnesota, and Mississippi, where fringe groups were able to acquire dangerous viruses, pathogens, and toxins, but fortunately were stopped before a domestic terrorism incident occurred.

Mr. Chairman, I would like to submit the rest of my statement for the record. I know that you have different rules over here on the Senate side than we do in the House. Due to the fact that the antiterrorism bill, it appears, will be coming up shortly, I think the version of the legislation that we have tried to draft would fit into and be germane to the antiterrorism legislation. Mr. Kasich was enormously helpful in trying to make certain that that would be accepted, and I would recommend, if it is possible—I know you might be able to do some things over on the Senate side that might be able to encompass some of the legislation that Mr. Markey has been able to develop.

Nonetheless, I do think that the second piece of this is a series of issues that could be taken care of on a very, very fast track.

I appreciate your willingness to hold this hearing and to listen to this Kennedy versus the other one. [Laughter.]

The CHAIRMAN. Actually, I listen to the other one all the time. Representative KENNEDY. I know that.

The CHAIRMAN. It is kind of a pleasure to listen to you.  
 Representative KENNEDY. I will tell Teddy you said that.  
 The CHAIRMAN. I am sure you will. [Laughter.]  
 But he knows that.  
 [The prepared statement of Mr. Kennedy follows:]

PREPARED STATEMENT OF REPRESENTATIVE JOSEPH P. KENNEDY II

Mr. Chairman, thank you for the opportunity to testify this morning on the subject of biological and chemical weapons and the potential threat to the American public. I very much appreciate your interest in this issue.

But before I begin, I'd like to acknowledge the good work of my colleagues John Kasich and Ed Markey with me here this morning. Together, we have developed two pieces of legislation: (1) the first measure deals with access to etiological agents, also commonly referred to as pathogens, toxins, or disease organisms, and (2) the second measure deals with the appropriate criminal punishments when these agents are used as a weapon of mass destruction to cause death or inflict harm or damage.

John Kasich, Ed Markey and I will be introducing legislation on biological weapons and intend to offer amendments to the comprehensive anti-terrorism legislation scheduled for consideration before the House of Representatives next week.

The Kennedy-Kasich-Markey "Biological Weapons Restrictions Act of 1996" would add provisions recommended by the Federal Bureau of Investigations, the Justice Department, and the Centers for Disease Control (CDC) to current law on weapons of mass destruction and biological and chemical weapons by making the criminal misuse of such biological organisms a federal crime.

On the surface, the bipartisan Kennedy-Kasich-Markey legislation is very basic. But it represents some very fundamental and necessary changes to current law to fill some very clear gaps identified by the FBI and Justice Departments.

Specifically, the bill and amendment would amend the federal criminal statute to impose mandatory penalties against anyone who knowingly develops, produces, stockpiles, transfers, acquires, or attempts to acquire under false pretenses any biological agent, toxin or delivery system for use as a weapons, or knowingly assists a foreign state or an organization to deliver a "weapon of mass destruction" intended to kill, injure or otherwise harm anyone living in the United States.

In closing, I'd also like to offer my support for the other approach developed by Representative Markey, myself, and others.

Congressman Markey's legislation would allow the Centers for Disease Control to develop regulations limiting the relative easy access to these dangerous biological agents to those individuals with insincere motives and illegitimate intentions, while also protecting the very sincere and legitimate scientific research involving pathogenic or etiological material.

There is obviously legitimate day-to-day research involving these dangerous viruses, such as efforts to find an antidote to the Ebola virus, ongoing at dozens, if not hundreds of academic laboratories. This research is ongoing at both Harvard University and Massachusetts Institute of Technology (MIT) in my congressional district. We must take the appropriate steps to protect this legitimate research, and I believe the Markey bill is a reasonable step in that direction.

Again, I appreciate the opportunity to testify this morning and I would be happy to take any questions the committee may have for me.

Thank you.

The CHAIRMAN. This is the book written by Robin Cook. I happen to think Robin Cook is a really interesting author. He is a full-blooded ophthalmologist and he writes well on these medical issues, but this is a bestseller today and it happens to deal with this issue. I don't mean to keep you two, but let me just read this one thing. I sent this to every one of you. Robin provided enough copies of this for every Member of Congress, I think, and I think I got them out to all. If I didn't get them to you, let me know.

Let me just read this to you. This is fiction, but it is really true. Well, I won't read the whole thing, but, "'Really,' Jack questioned. He had assumed that outside of the CDC and maybe a few academic centers, plague bacteria would be a rarity. 'Intermittently, labs have to get cultures of all different bacteria to test the efficacy

of their reagents,' Beth said, as she continued to work. Antibodies, which are often the main ingredient in many modern reagents, can deteriorate, and if they do, the tests would give false negatives. 'Well, of course,' Jack said. He felt stupid. He should have remembered all this. All laboratory tests had to be constantly checked."

"Where do you get something like plague bacteria?" 'From National Biologicals in Virginia,' Beth said. 'What's the process for getting it,' Jack asked. 'Just call up and order it,' Beth said. 'Who can do that,' Jack asked. 'Anybody,' Beth said. 'You're joking,' Jack said. Somehow, he thought the security, at a minimum, would be comparable to that involved in getting a controlled drug like morphine."

"I'm not joking, Beth said. 'I've done it many times.' 'You don't need some special permit,' Jack asked. 'I have to get the signature of the director of the lab on the purchase order,' Beth said, 'but that's just a guarantee that the hospital will pay for it.' 'So let me get this straight,' Jack said. 'Anyone can call these people up and have plague sent to them?' 'As long as their credit is OK,' Beth said. 'How do the cultures come,' Jack said. 'Usually, by mail,' Beth said, 'but if you pay extra and need it faster, you can get overnight service.' Jack was appalled, but he tried to hide his reaction. He was embarrassed at his own naivete. 'Do you have this organization's phone number,' he asked."

Now, fiction, but nevertheless really true. This is something that I want to commend both of you, and Congressman Kasich as well, for being leaders in this area because this is something that really has to be resolved, and that is the purpose for this hearing. I like your idea of putting it in the antiterrorism bill. Maybe we can do that. If you can do that on the floor, then we can maybe do any final touches to it that have to be done in conference.

Representative KENNEDY. I appreciate it, Mr. Chairman. If I just might, I understand you are having one of the lab test organizations from Maryland that, in fact, fits very nicely into Mr. Cook's description of what is, in fact, possible.

The CHAIRMAN. Right.

Representative KENNEDY. I think they ought to be commended. Whoever the fellow was, or woman, if you have got them, who works at that lab that caught the fellow from the Aryan Nations should be given a pat on the shoulder for a job well done. But leaving it to that kind of circumstance where there is a heads-up play by an individual who recognized that the way the request came in was a little bit abnormal and then gave a heads-up to the law enforcement agencies, I think, deserves commendation, but it also deserves the kind of action that I think this committee is anticipating in order to make certain that we don't leave it to that kind of twist of the wind in the future.

I appreciate, again, you and Mrs. Feinstein and Mr. DeWine's attention.

The CHAIRMAN. Well, thanks. You are both leaders in the House. We are honored to have you here. We appreciate you coming over. Any questions from any of you?

Senator FEINSTEIN. Mr. Chairman, I was just going to thank you. I know you sent that book. I just finished reading it. I read it through the night; I couldn't put it down.

The CHAIRMAN. It is a good book.

Senator FEINSTEIN. Then I began to really think—and you relate to what is happening out in the world—others read this book and what they might be able to go out and do, and it is very, very frightening. Particularly, their application of the human pathogens in the humidifiers—I mean, you can see the enormous harm that can be done.

So I want to congratulate both Congressmen Markey and Kennedy, and say I think there really is a need to take a good look. I am interested to hear what the labs will say, as well as CDC, and hopefully we can come up with a very tight set of regulations and controls.

The CHAIRMAN. Well, thank you. I have read all of Robin Cook's recent books, and I called him and I said, you are kidding about this, aren't you? He said, no, no. He said, this actually happens. I said, well, that is one reason we are leading to this.

So we appreciate your advance leadership on this and we will look forward to working with both of you and Congressman Kasich, as well. Thanks for coming. We appreciate it.

Representative MARKEY. Thank you, Senator.

Representative KENNEDY. Thank you very much.

The CHAIRMAN. Our second panel will be Mr. Mark Richard, the Deputy Assistant Attorney General of the Criminal Division. Mr. Richard will be joined by Mr. James M. Hughes, who is the Assistant Surgeon General and Director of the National Center for Infectious Diseases, Centers for Disease Control and Prevention, in Atlanta. So I am pleased to welcome you with us today and I look forward to your testimony a great deal.

We will begin with you, Mr. Richard. Welcome. We are always happy to have you guys up here.

**PANEL CONSISTING OF MARK M. RICHARD, DEPUTY ASSISTANT ATTORNEY GENERAL, CRIMINAL DIVISION, U.S. DEPARTMENT OF JUSTICE, WASHINGTON, DC; AND JAMES M. HUGHES, DIRECTOR, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GA, ACCOMPANIED BY STEPHEN A. MORSE, ACTING ASSOCIATE DIRECTOR FOR LABORATORY SCIENCE, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION**

#### **STATEMENT OF MARK M. RICHARD**

Mr. RICHARD. Thank you, Mr. Chairman and members of the committee. It is always a pleasure to be here. My name is Mark Richard. I am a Deputy Assistant Attorney General in the Criminal Division, and among my other duties is to oversee our Terrorism and Violent Crime Section, our Internal Security Section, and our Office of International Affairs.

With your permission, Mr. Chairman, I would like to submit my formal statement for the record and merely summarize some points.

The CHAIRMAN. Without objection, we will put it in the record.

Mr. RICHARD. In June 1995, as you already noted, Federal authorities in Ohio prosecuted Larry Wayne Harris for obtaining vials

of the plague bacteria by false and fraudulent pretenses from a commercial supplier of biological cultures to the scientific community. The case raised serious questions for law enforcement regarding the ease with which an individual in this country may obtain dangerous biological organisms.

An interagency task force was created last year to determine whether more rigorous controls over the sale, transfer, acquisition, and possession of dangerous biological organisms were appropriate. Among its findings, the group determined that there are no comprehensive Federal regulations governing the control of these dangerous organisms.

Currently, HHS has directed the Centers for Disease Control and Prevention and the Office of Emergency Preparedness to chair an interdepartmental committee to address the issue. The Department of Justice and the FBI are actively participating in that committee to help fashion a regulatory framework that will be imposed on restricted biological agents and will satisfy the needs of law enforcement.

In addition, the Department of Justice has studied applicable Federal criminal statutes to determine whether any legislative revisions are necessary to assure that persons who develop or use biological organisms as a weapon will face severe and certain punishment. In this regard, we have concluded that two provisions in title 18 should be amended to achieve that purpose.

I am also interested, Mr. Chairman and members of the committee, in studying the proposals by the Congressmen to see whether they are appropriate in the Department of Justice.

The CHAIRMAN. We would appreciate you really looking these over because we are in the process of developing ours and we would appreciate any help you can give us.

Mr. RICHARD. Yes. They are intriguing, as described by the Congressmen, and I look forward to working—

The CHAIRMAN. We also have heard that they are suggesting we put it in the antiterrorism bill, which is a matter of weeks away, so I think it is something we really need to jump on.

Mr. RICHARD. Yes. I agree with you, Mr. Chairman.

The CHAIRMAN. OK.

Mr. RICHARD. Our evaluation at this point has suggested to us that sections 175 through 178 of title 18 relating to prohibitions with respect to biological weapons—that this provision can be augmented. In substance, the current provision makes it criminal to knowingly develop, produce, transfer, acquire or possess any biological agent, toxin, or delivery system for use as a weapon.

We will propose that this provision be strengthened to include an attempt, threat, and conspiracy provision within its scope. In addition, we will propose broadening the definitions of “biological agent”, “toxin” and “vector” in section 178 to cover biological products that can be engineered as a result of advances made in the field of biotechnology.

The second statute in title 18 is section 2332a which makes it a criminal offense to use a weapon of mass destruction. Under current law, a weapon of mass destruction is defined to include any weapon involving a disease organism. The Department of Justice will seek to expand that definition to include in its coverage the bi-

ological agents and toxins as defined in section 178, including bio-engineered products that can be used as a weapon of mass destruction. In addition, we will seek to add a threat provision to this statute.

The draft regulatory framework proposed by HHS and my colleagues from that organization will testify to constitutes a first and very significant step toward a program that will be designed to adequately safeguard the public with respect to the sale, transfer, acquisition, possession, and use of dangerous biological organisms.

Many details need to be fleshed out of this structure or framework to assure that appropriate protections, such as accountability, auditability, and adequate Federal oversight of the program, are included in the regulatory provisions. The Department of Justice is working closely with HHS components to assure that the regulatory structure is rigorous in its control of dangerous biological agents and satisfies our law enforcement concerns.

In this regard, the Department agrees with HHS that it is imperative that every commercial and research laboratory that may legally handle restricted agents be listed in a registry subject to public review. In addition, we believe that the regulations should require that a record of each transaction of controlled biological agents be placed in a central repository which can be accessed by appropriate investigative agencies, such as the FBI, on a real-time basis. That registry must be open 24 hours a day and be available for immediate access by law enforcement. Further, a comprehensive scheme of felony criminal penalties and stiff civil penalties is necessary to help assure that compliance with any such regulatory structure be achieved.

While the specific criminal enforcement provisions that will complement the regulatory framework proposed by HHS must await the promulgation of the regulations, the Department of Justice will suggest that a felony offense be incorporated in title 42 for a willful violation of the regulatory provisions.

In addition, any person who willfully obtains a registration number, permit or other authorizing document under the regulations by means of false, fictitious, and fraudulent statements or representations should face significant felony penalties. Similar significant penalties should apply to the willful forging, counterfeiting, altering, or defacing of a required document or record. With respect to civil penalties, the Department of Justice has recommended a civil monetary penalty scheme that would apply to non-willful violations of the regulations to be imposed in the discretion of the HHS.

In sum, the Department of Justice and FBI seek to close the significant gap in Federal regulatory controls that the *Harris* case demonstrates. It is our purpose to work with our colleagues in other agencies, including HHS, as well as with the Congress to devise an appropriate scheme.

Thank you, Mr. Chairman and members of the committee. I would be glad to answer any questions you may have.

The CHAIRMAN. Thank you so much, Mr. Richard.

[The prepared statement of Mr. Richard follows:]

## PREPARED STATEMENT OF MARK M. RICHARD

Mr. Chairman and members of the Committee, my name is Mark M. Richard, and I am a Deputy Assistant Attorney General in the Criminal Division of the U.S. Department of Justice. It is my privilege to appear before you today in connection with the Committee's hearing on the interstate transportation of human pathogens.

In June, 1995, federal authorities in Ohio prosecuted Larry Wayne Harris for obtaining vials of *Yersinia pestis*, or the plague bacteria, by false and fraudulent pretenses from a commercial supplier of biological cultures to the scientific community. The matter was resolved by the defendant pleading guilty to a felony charge in accordance with a plea agreement. However, the case raised serious questions for law enforcement regarding the ease with which an individual in this country may obtain dangerous biological organisms. In fact, the *Harris* case demonstrated that presently there are inadequate federal controls, including regulations and criminal penalties, over the interstate sale, transfer, acquisition, and possession of organisms that, placed in the wrong hands, can be used to manufacture biological weapons of mass destruction.

As a result of the *Harris* case, an interagency task force was created last year to determine whether more rigorous controls over the sale, transfer, acquisition, and possession of dangerous biological organisms were appropriate. The Department of Justice and the Federal Bureau of Investigation (FBI) participated in the work of that group. Among its findings, the group determined that there were no comprehensive federal regulations governing the control of these dangerous organisms.

Currently, the Department of Health and Human Services (HHS) has directed the Centers for Disease Control and Prevention and the Office of Emergency Preparedness to chair an interdepartmental committee to address this issue. The Department of Justice and the FBI are actively participating on that committee to help fashion a regulatory framework that will be imposed on restricted biological agents. We are working closely with HHS to formulate suitable criminal and civil enforcement provisions to complement the regulatory structure that will be promulgated.

In addition, the Department of Justice has studied applicable federal criminal statutes to determine whether any legislative revisions are necessary to assure that persons who develop or use biological organisms as a weapon will face severe and certain punishment. We have concluded that two provisions in Title 18 should be amended to achieve that purpose.

Sections 175 to 178 of Title 18 relate to prohibitions with respect to biological weapons. In substance, this provision makes it criminal to knowingly develop, produce, transfer, acquire, or possess any biological agent, toxin, or delivery system for use as a weapon. It also prohibits knowingly assisting a foreign state or organization to do so. We will propose that this provision be strengthened to include an attempt, threat, and conspiracy prohibition within its scope. In addition, we will propose broadening the definitions of biological agent, toxin, and vector in Section 178 to cover biological products that can be engineered as a result of advances made in the field of biotechnology.

The second statute in Title 18 is Section 2332a. That provision makes it a criminal offense to use a weapon of mass destruction. Under current law, a "weapon of mass destruction" is defined to include "any weapon involving a disease organism." 18 U.S.C. § 2332a(b)(2)(C). The Department of Justice will seek to expand that definition to include in its coverage the biological agents and toxins, as defined in Section 178, including bioengineered products, that can be used as a weapon of mass destruction. In addition, we will seek to add a threat provision to this statute.

The draft regulatory framework proposed by HHS in its testimony before this Committee constitutes a first step towards a program that will be designed to adequately safeguard the public with respect to the sale, transfer, acquisition, possession, and use of dangerous biological organisms. Many details need to be fleshed out to assure that appropriate protections, such as accountability, auditability, and adequate federal oversight of the program, are included in the regulatory provisions. The Department of Justice is working closely with HHS to assure that the regulatory structure is rigorous in its control of dangerous biological agents, and satisfies the concerns of law enforcement.

The Department of Justice agrees with HHS that it is imperative that every commercial and research laboratory that may legally handle restricted agents be listed in a registry subject to public review. In addition, we believe that the regulations should require that a record of each transaction of controlled biological agents be placed in a central repository, which can be accessed by appropriate investigative agencies, such as the FBI, at any time. It is crucial that the FBI have immediate access to such records in the event of an incident involving a biological weapon. Fur-

ther, a comprehensive scheme of felony criminal penalties and stiff civil penalties will help assure that compliance is achieved.

While the specific criminal and civil enforcement provisions that would complement the regulatory framework proposed by HHS must await the promulgation of the regulations, the Department of Justice has suggested that a felony offense be enacted in Title 42 for the willful violation of the regulatory provisions. In addition, any person who willfully obtains a registration number, permit, or other authorizing document under the regulations by a false, fictitious, or fraudulent statement or representation should face felony penalties. Similar penalties should apply to the willful forging, counterfeiting, altering or defacing of a required document or record.

With respect to civil penalties, the Department of Justice has recommended a civil monetary penalty scheme that would apply to non-willful violations of the regulations, to be imposed in the discretion of the Secretary of the Department of Health and Human Services. Other civil penalties may also be sought in appropriate circumstances. For example, an institution that violates the regulations may face suspension of future federal grants. We will work with HHS to impose the most effective civil penalties that will help assure compliance with the regulations.

In sum, the Department of Justice and the FBI seek to close the significant gap in federal regulatory controls that the *Harris* case demonstrated exists today. It is our purpose to prevent persons with criminal intent from obtaining access to dangerous biological agents in the normal stream of commerce. We are committed to continue working with HHS to develop a regulatory plan that most effectively achieves that purpose. In addition, we will seek the legislative changes in the Title 18 provisions that I have outlined in my testimony to help assure that the development and use of biological weapons be subject to severe criminal penalties.

In conclusion, I want to thank the Chairman for this opportunity to appear before the Committee on this issue of major importance. I would be happy to answer any questions that the Committee might have.

The CHAIRMAN. Dr. Hughes, we will turn to you. We have set the 5-minute time. If you can summarize, we would appreciate it. We are going to put all written statements as though fully delivered into the record. So we appreciate that.

### STATEMENT OF JAMES M. HUGHES

Dr. HUGHES. Thank you very much, Mr. Chairman. Good morning. I am Dr. James Hughes, Director of the National Center for Infectious Diseases at the Centers for Disease Control and Prevention. I am accompanied by Dr. Stephen Morse, who is our Acting Associate Director for Laboratory Science.

The CHAIRMAN. Welcome to the committee.

Dr. HUGHES. We are pleased to be here to discuss interstate transportation of human pathogens. CDC serves as co-chair of an interdepartmental committee working to develop a framework for controlling the acquisition and transfer of infectious agents. I will describe the composition of that committee, its charge, and the proposed framework.

The Department of Health and Human Services has been designated to be the leader for developing plans for the medical consequences of terrorism with biological and chemical weapons of mass destruction. This mission was made all the more imperative by the recent episode involving the individual who was able to obtain the pathogen-causing plague at his private residence in Ohio.

In the summer of 1995, the Office of Emergency Preparedness and HHS convened an interdepartmental work group to review the existing system under which organisms are safeguarded from inappropriate use, yet made available for necessary scientific work. Based on this informal review, Dr. Philip Lee, HHS Assistant Secretary for Health, directed CDC and OEP to co-chair a committee

composed of representatives from within HHS, as well as other departments and agencies, including the Department of Justice.

The committee's charge is to prepare an overview of regulations governing the shipment of infectious agents, to prepare a list of infectious agents that would be monitored when shipped, to develop a legal framework for enforcement related to the acquisition and shipment of these restricted agents, and to consider whether a registry for tracking restricted recombinant DNA materials is needed. This committee is also considering approaches to strengthening criminal penalties for the illicit use of these agents.

Present safeguards may appear inadequate, but they must be evaluated taking into consideration the historical perspective of how successful they have been. Even in the recent episode involving the plague bacillus, the existing voluntary safeguards resulted in alerting Federal officials and safe retrieval of the material by local authorities. The goal is to strike a balance between assuring the availability of materials to the scientific community and preventing access to these agents for other than legitimate scientific purposes.

Existing criminal laws can be strengthened, and these enhancements have been described for you by my colleague from the Department of Justice. I would like to describe one possible framework that has been proposed and is under discussion by the inter-departmental committee. We have informally discussed this framework with colleagues in the research community and the response has generally been supportive.

We are committed to reaching closure on the details of a framework and publishing a notice of proposed rulemaking within 180 days. We will be prepared to modify this proposal in response to public comments. After implementation, we will assess the effectiveness of this framework and refine and/or strengthen the process as necessary.

To be successful, the proposed framework should focus on strengthening public-private sector accountability through involvement of professional organizations in coordination with the research community, minimize the burdens of additional Federal regulatory structure, and dovetail with expanded Federal criminal sanctions.

Specifically, the proposed framework would collect and provide information concerning the locations where specific, potentially hazardous microorganisms are used, track the acquisition and transfer of the specific microorganisms, and establish a process for alerting appropriate authorities if an unauthorized attempt is made to acquire these agents. These proposals can be implemented under existing HHS statutory authority by making appropriate modifications to the current CDC regulations governing the interstate shipment of etiologic agents.

In addition to assuring proper controls, prompt detection of infectious threats requires careful monitoring by effective disease surveillance and response systems. CDC's plan addressing emerging infectious disease threats is the foundation for CDC's surveillance and response strategy for responding to infectious disease threats.

A recent report of the CISET working group on emerging and re-emerging infectious diseases emphasized that a global infectious

disease surveillance and response network is essential to enable us to respond effectively in the event of an attack involving biological agents. These reports have been provided to the committee.

Implementation of a framework for controlling the acquisition and transfer of infectious agents, together with the CDC plan and the Ciset work group recommendations, will help the public health system identify and control infectious diseases before they cause widespread epidemics. Infectious diseases will remain important, evolving, complex public health problems. To meet the challenges posed by infectious diseases and threats of biological terrorism, we must strengthen our capacity to detect and respond to emerging infectious diseases. The proposed framework will provide effective controls for the acquisition and transfer of dangerous pathogens, and will also ensure that these agents will be available for legitimate scientific research purposes.

Thank you very much for the opportunity to testify before the committee. I will be happy to answer any questions you may have.

[The prepared statement of Dr. Hughes follows:]

#### PREPARED STATEMENT OF JAMES M. HUGHES

Good morning, I am Dr. James M. Hughes, Director of the National Center for Infectious Diseases (NCID), Centers for Disease Control and Prevention (CDC). I am accompanied by Dr. Stephen A. Morse, Acting Associate Director for Laboratory Science, NCID. We are pleased to be here to discuss interstate transportation of human pathogens and their control and acquisition. CDC serves as co-chair of an interdepartmental committee working to develop a framework for controlling the acquisition and transfer of infectious agents. My statement will describe the composition of that committee, its charge, and the proposed framework.

In recent years, the threat of biological terrorism has become an area of increasing concern from the perspective of both public health and domestic security. As part of the comprehensive preparations underway to address emerging terrorist threats, the President designated the U.S. Department of Health and Human Services (HHS) to be the leader for developing plans for the medical consequences of terrorism with weapons of mass destruction. The timeliness of this mission was made all the more imperative by the recent disclosure that an individual in Ohio was able to order and receive at his private residence three vials of lyophilized pathogen, *Yersinia pestis* (plague bacillus).

In the summer of 1995, the Office of Emergency Preparedness (OEP) within HHS convened an informal, interdepartmental workgroup of federal scientists and health professionals to review the existing system under which organisms are safeguarded from inappropriate use, yet made available for necessary scientific work. Specifically, the workgroup (1) reviewed the current safeguards for the sale of Biosafety Level 3 and Biosafety Level 4 organisms; (2) reviewed the safety procedures for registry and sale of recombinant DNA products; (3) reviewed the adequacy of shipment controls for Biosafety Level 3 and Biosafety Level 4 organisms; and (4) collated and reviewed the adequacy of the current laws and regulations governing the interstate and international acquisition and shipment of Biosafety Level 3 and Biosafety Level 4 organisms.

Based on this informal review, Dr. Philip Lee, the HHS Assistant Secretary for Health, directed CDC and OEP to cochair a committee composed of representatives from CDC, the Food and Drug Administration, the National Institutes of Health, OEP, and to invite participation from the U.S. Departments of Commerce, Defense, Justice, and Transportation, the Environmental Protection Agency, and the U.S. Postal Service.

The charge to this committee is to (1) prepare an overview integrating the regulations governing the shipment of infectious agents in interstate commerce; (2) prepare a single list of infectious agents that would be used by the Federal government to monitor the shipment of these agents in interstate commerce; (3) develop a legal framework for enforcement of Federal regulations related to the acquisition and shipment of these restricted agents; and (4) consider whether a registry for tracking the purchase of restricted recombinant DNA materials is needed. As part of its charge, this committee is looking at strengthening criminal penalties for the illicit use of these agents.

## THE CURRENT SYSTEM

In the 1960's and 70's, the CDC published editions of the Classification of Etiologic Agents on the Basis of Hazard, which were lists of infectious microorganisms categorized by potential severity of laboratory-acquired infection. This publication became the basis for establishing the CDC/NIH guidelines (Biosafety in Microbiological and Biomedical Laboratories) published first in the 1980's and updated periodically, as well as the NIH Guidelines for Research Involving Recombinant DNA Molecules. These documents have become the "gold standard" for the safe conduct of biohazardous research throughout the U.S. (and in several foreign countries).

The current safeguards governing the acquisition and distribution, in the United States, of infectious and/or toxic agents are not comprehensive. There is no single set of consistent regulations but rather a number of different departmental regulations that address the shipping and handling of infectious agents. Taken together, these are effective at controlling the packaging, labeling, and transport of infectious materials, but they are not completely effective at controlling the possession and transfer of human infectious agents within the United States.

Within existing research facilities the handling of human infectious agents are safeguarded by institutional biosafety officers or biosafety committees guided by the principles and criteria described in the CDC and NIH manual, Biosafety in Microbiological and Biomedical Laboratories and the NIH Guidelines for Research Involving Recombinant DNA Molecules. However, there is no central registry of existing laboratories that handle these agents, no means of knowing the number or location of Biosafety Level 3 and Biosafety Level 4 facilities, and no means for ensuring that the laboratories are adhering voluntarily to the principles found in CDC and NIH guidelines.

These safeguards may appear inadequate in the context of today's focus on biological terrorism, but they must be evaluated taking into consideration the historical perspective of how successful they have been. Estimates of the interstate transfer of dangerous human infectious agents for legitimate scientific research among academic and commercial institutions range from several hundred to a few thousand per year. And, despite those numbers, only the single episode of the inappropriate transfer in Ohio last year has been reported. Moreover, it is important to note that even in the Ohio instance, the existing voluntary system of safeguards resulted in the alerting of federal officials and the safe retrieval of the unopened, intact vials by local authorities.

We believe breaches of existing safeguards for these agents have rarely occurred and the current goal is to strike a balance between assuring the availability of infectious and recombinant DNA materials to the scientific and medical community for important public health and biotechnological research and preventing access to these agents for other than legitimate scientific and medical purposes.

## PRINCIPLES AND COMPONENTS OF THE HHS DRAFT PROPOSED FRAMEWORK

While recognizing that it is possible for a determined terrorist to circumvent almost any system regulating the acquisition and transfer of dangerous pathogens, existing criminal laws concerning the use of biological weapons can be strengthened, and these enhancements will be described for you by my colleague from the Department of Justice.

I would like to describe one possible framework that has been proposed and is under discussion by the interdepartmental committee under which a policy for controlling the safe acquisition and transfer of infectious human agents will be developed, reviewed, and implemented. We already have informally discussed this framework with a number of interested parties in the research community, and the reaction has generally been supportive. However, it's important to note that this proposal is still under discussion and that many of the specifics remain to be decided. To ensure that we continue our progress in protecting the public health, we are committed to reaching closure on the detailed aspects of the following framework and publishing, within 180 days, a Notice of Proposed Rule Making. In accordance with the Administrative Procedures Act, we will fine tune the proposal in response to the public comments.

In developing our proposed framework, we were guided by a number of key principles beyond that of ensuring that the public safety is protected without encumbering legitimate scientific and medical research. To be successful, the proposed framework should:

- focus on strengthening public-private sector accountability through involvement with professional associations and coordination with the research community;
- minimize the burdens of an additional, expansive federal regulatory structure; and

- dovetail with expanded federal criminal sanctions.

As part of this framework, we are proposing to develop: (1) a comprehensive list of "restricted" infectious agents; (2) a unique registration of laboratories handling these restricted agents; (3) transfer requirements; (4) verification procedures; (5) agent disposal requirements; and (6) research and clinical exemptions. Specifically, the proposed framework would:

- collect and provide information concerning the location where specific potentially hazardous microorganisms are used;
- track the acquisition and transfer of these specific microorganisms; and
- establish a process for alerting appropriate authorities if an unauthorized attempt is made to acquire these agents.

These proposals can be implemented under existing HHS statutory authority (42 USC 264) by making appropriate modifications to the current CDC regulations governing the "Interstate Shipment of Etiologic Agents" (42 CFR Part 72).

#### *Restricted agent list*

A "restricted" agent list would be composed of those agents that have the potential to pose a severe threat to the public health. The proposed list would be compiled after consultation with experts representing appropriate professional groups and updated as needed.

#### *Unique registration of laboratories handling restricted agents*

Commercial suppliers of these restricted agents, as well as universities, research institutes and companies that are working with these agents, or that want to work with these agents, would be required to register with an organization approved by the Secretary, and obtain a unique site registration number. Registration would require the applicant institution to certify that its laboratory or laboratories meet the Biosafety Level 3 and/or Biosafety Level 4 standards for working with dangerous pathogens as described in the 3rd edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories manual and the NIH Guidelines for Research Involving Recombinant DNA Molecules.

Under this proposed framework, we believe that the function of registering institutions and assigning unique registration numbers could be accomplished by a non-governmental, professional organization authorized by the Secretary, HHS. Moreover, the framework envisions the registration process to be self-supporting through collection by the organization of a site registration fee. Each institution's unique registration number would be used to help validate all requests for transfer of dangerous human pathogens.

#### *Transfer requirements*

A simple, approved government form should be developed to aid in tracking requests for restricted agents. All transfers of restricted agents would require this form to be completed in advance of any shipment. This form would include the list of restricted agents and would require information about the requestor as well as the transferor, including their registration numbers, the restricted agent requested, and the proposed use of the agent. It would be required that this form accompany the purchase order and requests for obtaining restricted agents, and that a copy be maintained in a designated central repository which would be available to the FBI and other appropriate authorities. Falsification of this form would be a federal criminal offense.

#### *Verification procedures*

The requestor's responsible institutional official would have to sign each request, certifying that the researcher is officially affiliated with the institution and that the laboratory meets current CDC/NIH Guidelines for working with the requested agent. The responsible institutional official sending the restricted agent would be required to verify that the recipient holds a current registration number, indicating that the recipient has Biosafety Level 3 or Biosafety Level 4 capacity. Inability to validate the necessary information would result in notification of the appropriate authorities. Copies of the completed form would be kept by both the requestor's and transferor's institution. Receipt of a restricted agent would have to be acknowledged by the recipient. Institutions would be given specific instructions on how to report suspicious requests to appropriate authorities.

#### *Agent disposal requirements*

There would be a statement on the form that the infectious agents must be stored under secure conditions and destroyed after completion of the work or transferred to an approved repository. Institutions should have in place procedures for the appropriate disposal of the agents.

### *Research and clinical exemptions*

In order to provide strains for reference diagnostic and research studies at Biosafety Level 2 facilities, less pathogenic strains such as vaccine strains of restricted viral agents as described in the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories manual should be exempted from the list of restricted agents. Transportation of clinical specimens for diagnostic and verification purposes also must be exempt. However, isolates of restricted agents from clinical specimens should be destroyed after confirmation or sent to an approved repository after diagnostic procedures have been completed. Other than for the purposes I've indicated, such isolates could not be transferred to another site without using the transfer form and approval by the responsible institutional officials.

### OTHER SURVEILLANCE AND RESPONSE SYSTEMS FOR INFECTIOUS THREATS

In addition to assuring proper controls for these pathogens, prompt detection of infectious threats requires careful monitoring by effective surveillance and response systems. Like radar or "early warning" systems that detect threats to national security, surveillance with appropriate laboratory support is critical to an effective defense against infectious diseases. Since 1994, CDC has focused on implementing its plan, Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States. The plan contains specific goals based on recommendations from the National Academy of Science's Institute of Medicine, which documented that the capacity of the U.S. public health system is in jeopardy. This plan is the foundation for CDC's domestic and international surveillance and response strategy for infectious disease threats.

During 1995, a U.S. government interagency working group, including representatives from almost 20 different agencies, reviewed the U.S. role in detecting and responding to outbreaks of infectious diseases. Dr. David Satcher, Director of CDC, chaired this working group, established under the aegis of the Committee on International Science, Engineering, and Technology (CISST) of the National Science and Technology Council. The CISST working group report, Infectious Disease—A Global Health Threat, released in July 1995, made nineteen recommendations for action by the U.S. government. The report emphasized that a global disease surveillance and response network could enable the United States to respond quickly and effectively in the event of an attack involving biological or chemical warfare, and noted that the experience gained in controlling naturally occurring microbes will enhance our ability to cope with a biological warfare agent, should the need arise. The release of nerve gas in the Tokyo subway system in March 1995 has underscored our need to be well prepared to counteract deliberate attempts to undermine human health.

Implementation of a framework for controlling the acquisition and transfer of infectious agents, together with the CDC plan Addressing Emerging Infectious Diseases and the CISST working group recommendations on infectious disease, will help the public health system identify, control, and prevent infectious diseases before they cause widespread epidemics.

### CONCLUSIONS

Infectious diseases will remain important, evolving, complex public health problems. To meet the challenges posed by infectious diseases and threats of biological terrorism, we must strengthen our capacity to detect and respond to emerging infectious diseases. The proposed framework will provide effective controls for the acquisition and transfer of dangerous human pathogens. This framework will help ensure that these agents will be available for legitimate scientific purposes and will protect against attempts to obtain these agents for illicit purposes.

Thank you for the opportunity to testify before the committee. I will be happy to answer any questions you may have.

The CHAIRMAN. Well, thank you so much.

Dr. Hughes, can you briefly explain to the committee the biosafety levels that exist now and how CDC classifies human pathogens? You have made reference to it in your remarks, but I would like to—I understand that most of the recent revision of the CDC classification of human pathogens was published in 1993. I want to know if that is correct, and are there reasons that the classification system should be updated more frequently to reflect current science? In that regard, we have this biohazard levels chart over here that might be of some help to you.

Dr. HUGHES. Yes, I think that will be quite helpful to all of us. These four biosafety levels are outlined in the CDC-NIH manual called "Biosafety in Microbiological and Biomedical Laboratories" which we can submit for the record. You are correct, sir. The current version of this manual was published in 1993.

The four biosafety levels are outlined there. The highest biosafety level is Biosafety 4. That involves agents that must be worked on under maximum containment laboratory conditions. There are two such facilities in this country, one at CDC and one at the DoD facility at Fort Detrick.

The next lower level is Biosafety Level 3. That involves agents that are also dangerous in laboratory settings. Infection can be acquired through needle stick transmission or through inhalation. In general, for agents classified at the Biosafety Level 3, effective treatment or vaccines are available.

Biosafety Level 2 is the level at which most work is done in clinical microbiology laboratories. That involves the vast majority of infectious agents that cause disease, but that do not pose great risks to laboratory workers. Biosafety Level 1 actually rarely comes into play. That involves work done on microorganisms that are not known to cause human disease.

The CHAIRMAN. I can't read that last block there. It says "Hazard to personnel relate to any contact with the agent, including"——

Dr. HUGHES. Aerosol contact.

The CHAIRMAN. Aerosol contact.

Dr. HUGHES. Inhalation of aerosols.

The CHAIRMAN. Do you have a stronger level than 4 where we get into anthrax and some of these other——

Dr. HUGHES. No. 4 is the highest level and it is the level, for example, that Ebola is worked on and that Lassa fever virus is worked on at CDC. Level 4 agents are those that cause serious infections, primarily viral hemorrhagic fevers.

The CHAIRMAN. But the pathogen that causes the plague is in—— is it in 2?

Dr. HUGHES. Depending on the type of work that is being done with it, it would be either at Level 2 or at Level 3. If it is being worked with in large volumes or high concentrations where you would be concerned about the possibility of aerosol generation, it would be worked on at Biosafety Level 3.

The CHAIRMAN. OK. Now, for all three of you, to date, who outside of the Government has had input into the development of the specific approaches to this issue, to the guidelines that CDC will propose, and what are the Administration's plans to solicit input from involved parties before development of the specific details to your plan?

Dr. HUGHES. OK, let me speak to that initially and then refer to my colleagues. We have consulted to date informally with members of the research community and with some members of State public health departments about the proposed framework that we have outlined here. We need much more input into this, and that is planned as we move forward. But as I mentioned in my statement, the preliminary reaction of people in the research community that we have talked with, as well as people in State public health departments, has been supportive.

The CHAIRMAN. I understand the preliminary reaction is that the clinical laboratory community feels that adequate safeguards exist with the current regulatory scheme for clinical laboratories. Do you agree with that?

Dr. HUGHES. I think for clinical laboratories, the existing safeguards are reasonable, but again that will—

The CHAIRMAN. Do we need to enhance those protections with regard to human pathogens?

Dr. HUGHES. Well, I think we always are looking for ways in which we can minimize the risk of transmission of infectious agents in laboratory settings to laboratory workers.

The CHAIRMAN. You have been working on this issue for now over 8 months. Why do you need another 6 months before you publish your proposed regulations? I thought this was the CDC, not the FDA. [Laughter.]

I couldn't help but take that shot.

Dr. HUGHES. I won't comment on the last statement.

The CHAIRMAN. Any time I can prod my colleagues out at FDA, I am going to do it.

Dr. HUGHES. We have thought a lot about this, Senator. It is a very complicated issue. There are lots of Federal agencies involved in this, as I think you know. There is a large number of existing regulations that govern interstate, and indeed international transfer of these agents. There is no question that those need to be harmonized and, in my view, there is no question that the whole system needs to be tightened up to minimize the risk that transfers of these pathogenic agents to inappropriate persons occurs.

The CHAIRMAN. We have allowed 5 minutes for questions for each of us. My time is just about up. Would you provide for the record a list of the outside groups you consult with, or you have already consulted with?

Dr. HUGHES. Yes, we would be happy to do that.

The CHAIRMAN. I would appreciate that.

[The information referred to was not available at presstime.]

The CHAIRMAN. Then last but not least, is new legislation needed to regulate the interstate transportation of human pathogens, or do the current laws give you sufficient regulatory authority?

We will go to you, Mr. Richard.

Mr. RICHARD. Well, I think new legislation is needed in this area.

The CHAIRMAN. Certainly, in the area of penalties, and so forth.

Mr. RICHARD. Yes, and depending on the structure that is ultimately designed, I think we are going to have to ensure that there is adequate enforcement capability. Like I said, I think we must look at both civil and criminal in that regard.

The CHAIRMAN. Well, two things. Do you believe that the possession of these strains by individuals who have no known scientific or medical interest in the pathogen should be illegal, and what about the knowing sale of these materials to individuals or groups who have no legitimate need for them?

Mr. RICHARD. Certainly, the whole distribution network, I think, has to be controlled, and to the extent that there is evidence to suggest that it is being used for illicit purposes, if you will, I think that has to be addressed.

The CHAIRMAN. So it has to be a knowing standard, then?

Mr. RICHARD. Yes, obviously, but we do think in the context of the regulatory process there should be capability of imposing sanctions for non-willful violation of the regs.

The CHAIRMAN. My time is up. Senator Feinstein has graciously agreed to allow Senator Thurmond to go next for one short question.

Senator THURMOND. I just want to ask you this. To make it very simple, do you favor legislation or do you favor going forward and feel you can handle it through regulation?

Dr. HUGHES. I feel the framework that we have outlined needs to be more fully developed and implemented. I think in terms of legislation, there clearly is a need to tighten up the overall system and make sure that criminal penalties are in place that can be enforced against people who inappropriately obtain or possess these—

Senator THURMOND. Which do you favor, legislation or further regulation?

Dr. HUGHES. I think from the standpoint of the regulatory framework that I have outlined, I would favor regulation.

Senator THURMOND. So you would favor that?

Dr. HUGHES. Yes.

Senator THURMOND. Thank you very much. Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Thurmond.

We will turn to Senator Feinstein.

Senator FEINSTEIN. Thank you, Mr. Chairman. I would like to know with specificity how it happened that an individual could order plague bacteria and have it delivered to their home.

Dr. HUGHES. I had not run across the book *Contagion* before. I think that the passage that Senator Hatch outlined indicates how that could happen.

Senator FEINSTEIN. No, no. I am speaking of a specific incident. Now, you all are the investigative authorities. How did it happen? How did that specific incident referred to on page 2 of your comments happen? From where was it ordered and how was it done, if I might ask?

Dr. HUGHES. Well, certainly, we know some of those details. Because that case is under litigation at the moment, let me ask Mr. Richard to speak initially to that.

Senator FEINSTEIN. It seems to me that would be the first thing you would all want to take a look at. How did it happen? What lab made it possible? How did someone order this kind of stuff? How did it come to his home?

Mr. RICHARD. Senator, as Dr. Hughes indicated, because the case is still in litigation, I would like to go more into the hypothetical, if I may, rather than discussing this specific event. I can tell you that in analyzing the whole continuum of the process, it has become apparent to us that there are significant gaps at all stages and that these gaps must be addressed.

Senator FEINSTEIN. Well, Mr. Chairman, if we need to go to a closed session, I would really like to know how it happens in the United States of America that just anybody can order plague bacteria and have it delivered to their home. I think before we get into a convoluted regulatory scheme, we ought to understand very

clearly and very definitely where the individual got the bacteria. Did it come from a private lab? If so, what is the situation that someone can just order this stuff willy nilly? I mean, I think it is appalling to find out that anybody can—was it done by phone, was it done by mail? Did he falsify credentials? I would like to know that.

Mr. RICHARD. I think we can describe the current system where an individual can seek to acquire this. I think we can, in general, describe that here, if you wish, ma'am.

The CHAIRMAN. But you are also acknowledging the current system really needs some help.

Dr. HUGHES. It definitely needs some help, and this case clearly illustrates that. The specimens were ordered through the mail, as I understand it, from the American Type Culture Collection.

Senator FEINSTEIN. And is that a private collection, or what is the collection?

Dr. HUGHES. Well, Dr. Reller will be on the next panel and he is representing the American Type Culture Collection, so I would prefer to defer.

Senator FEINSTEIN. Well, could you not tell me what that is? Is it a private organization? Is it a government organization?

Dr. HUGHES. It is a private organization, as I understand it, that is a repository for many infectious agents and it makes those agents available to research laboratories or clinical laboratories.

Senator FEINSTEIN. Well, clearly, they send it out to anybody.

Dr. HUGHES. There was some misrepresentation involved in the way this order came in, as I understand it.

Senator FEINSTEIN. So, in other words, anybody that writes and says, I am a Ph.D. connected with xyz researching abc, can order plague bacteria to their home.

Dr. HUGHES. And submits appropriate paperwork that suggests the person is affiliated with an appropriate laboratory. Under the current system, that is correct, and that is what needs to be changed.

Senator FEINSTEIN. I will tell you, being from a long medical family, my very real view is that this stuff ought to be all closely restricted and regulated, and what I hate to see is us getting into a big, difficult regulatory scheme. It seems to me anybody working with highly contagious and lethal bacteria ought to be in very specific places, not all over the United States, not subject to being blackmailed, not subject to being bought out by somebody that wants to buy this stuff, because I think the potential—we have now seen it with the sarin; we have now seen it in my State with what people thought was going to happen at Disney. I think there is a very real reason to be very concerned.

I am concerned that you are going to put in an elaborate regulatory scheme that is still going to permit somebody, with fraud, to go and get this stuff, and I think it ought to be all highly restricted.

Dr. HUGHES. Well, we agree with you, and that is the purpose, really, of the framework that I outlined. It is described more fully in my written testimony that you have for the record, but we agree that a list of restricted agents needs to be developed and agreed

upon and we are proposing to do that in consultation with the appropriate professional societies and the research community.

We also feel very strongly that laboratories working on such agents on such a list need to be certified and need to be registered with a central registering authority, and that prior to each shipment of one of the agents on this list there needs to be certification by the primary researcher, as well as the institutional biosafety official, that conditions are such in those laboratories that the agent can be worked on safely, and obviously also that this is a legitimate research institution that is registered and certified. So we agree.

Senator FEINSTEIN. Yes, but my own view is that there should be very few people that are able to handle these materials and it should be a very limited list. I mean, we are talking about bacteria that is capable of killing hundreds of thousands of people, if put in the right place.

Dr. HUGHES. Well, we agree with you that when this system is put into place, there will be relatively few researchers with the capability and the interest in working on these organisms. Part of the problem in this country today is because of all the complacency that has developed around infectious diseases, a feeling that these diseases are largely controlled, there has been an erosion in expertise available to even work on these.

Senator FEINSTEIN. I am not complacent, sir.

Dr. HUGHES. Good.

Senator FEINSTEIN. I mean, I am not complacent at all.

Dr. HUGHES. I am not either.

Senator FEINSTEIN. I would be hopeful that this committee would not be. I don't think I would want to see a big regulatory scheme that enabled thousands of people to have fiercely lethal bacteria.

Dr. HUGHES. The scheme that we envision would not allow that.

Senator FEINSTEIN. I hope not. I mean, I couldn't tell. You get into Bio 1, Bio 2, Bio 3.

Dr. HUGHES. Well, Bio 1 you don't have to worry about.

Senator FEINSTEIN. I am anxious to have somebody from my Government say we are not going to let these kinds of agents be freely transmitted through the mail or bought in person. I guess that is the kind of reassurance I am interested in hearing.

Dr. HUGHES. Well, that is what I am trying to say that is what the framework is outlined to accomplish.

Mr. RICHARD. Senator, if I may interject in response, the indictment in the *Harris* case does reflect that he acquired the bacteria from a commercial supplier by means of utilization of a false letterhead and an identification of his employer's EPA identification number.

The most startling aspect of this whole situation is that at the present time it is not illegal under existing law merely for a person to order such materials. What the current system relies upon is the supplier to make a judgment in accord with internal policy, not necessarily by regulation, government law, or anything, but by internal policy that this is a bona fide request and utilization by someone who is qualified to utilize this.

Obviously, that is a deficient system and one that is startling in its implications, but the response is how best to set up, with minimum burden, but nevertheless with effectiveness, a system to en-

sure, No. 1, that our first emphasis is on prevention of this material getting into questionable hands, and No. 2, providing methodologies for ensuring that we have a way of detecting illicit distribution and be able to investigate and apprehend quickly in the event that there is a problem. Right now, it is a system that from a law enforcement point of view is almost non-existent, so it cries out for a quick and very significant response.

Senator FEINSTEIN. Thank you very much. I thank you.

The CHAIRMAN. Well, as you can see, this is a—I agree with you it needs a quick response. I think one of the questions is if the administration knew about this problem, why hasn't more been done. Now, everybody knows about it and I have to say that I think Robin Cook does us a favor in writing about these things because some of us may or may not have known about this without the book.

So I think what we are saying is we have got to do two things. We have got to come up with regulations pretty darn quickly, not just so that the supplier that gets it happens to be qualified and safe, but that that material is tracked from that point on so that if that supplier goes out of business, as Senator Feinstein raises, or wants to sell its business or sell the pathogen or transfer it, there be very strict rules with regard to that as well.

We are talking about a terrorist age, and some of these pathogens could wipe out a whole office building, for instance. You know, we are talking about an age where people don't value human life anymore.

Senator FEINSTEIN. That is right.

The CHAIRMAN. I think it is very important that this is jumped right on and that we get the laws changed the way they should be, and I think we are going to count on you, Mr. Richard, and the people down there at Justice to help us to know what to do in the best way. We have got our own ideas, but we are certainly amenable to good ideas.

I think, Dr. Hughes, you have got to get the people there to concentrate on this and get the regulations out right away because this is startling to anybody, and now you have network TV who knows all about it, or will know all about it. I think that is probably a fair way to do it, to let people know this is a big problem.

Dr. HUGHES. I agree with you, Senator. I think it is important for the public to realize some of these risks that do exist.

Mr. RICHARD. On behalf of the Department of Justice, Mr. Chairman and Senator Feinstein, the Department is more than glad to work with you on this problem.

The CHAIRMAN. Well, we have a good relationship with the Department and we intend to keep it, and we really expect as much help as you can give to us on this, OK, and let's do it now.

Senator FEINSTEIN. Mr. Chairman, let me just ask, have any arrangements been put in on an emergency basis to prevent this from happening tomorrow or next week?

The CHAIRMAN. That is a good question.

Dr. HUGHES. That is a very good question. I think the awareness of the whole research community, and certainly those who supply agents to others, is heightened dramatically by this episode. So

there is no formal system in place to ensure that it doesn't happen again over the next few months, but—

Senator FEINSTEIN. You mean you cannot just arbitrarily stop the shipment of this stuff by mail order until we have something in place?

Dr. HUGHES. I suppose that could be done. The risk there would be inhibition of really high-priority ongoing scientific research. I think what can be done and is being done is careful assessment now. Certainly, at CDC, we are looking very carefully at any requests that we get for agents of this type.

The CHAIRMAN. Well, as I understand it, it isn't just CDC, but there are a number of other laboratories who have these pathogens which may or may not be controlled by the Government. Is that right?

Dr. HUGHES. That is true.

The CHAIRMAN. Well, I think you need to jump right on this. I think to the extent that you can come up with regulations that will help, that ought to be done. Now, I understand that is difficult, but I would rather come up with regulations as best we can now and continue to refine them than to wait for 8 months while perhaps some more of this is going to go on.

I agree with Joe Kennedy that if we can somehow or other put it in the antiterrorism bill, it belongs there and we ought to work to do that. I will say that that is done if it is possible, and I think it is. I think everybody is going to be happy if we pass a true antiterrorism bill even though it may not be exactly the way it was in the Senate. It will probably be shaved down a little bit because of trying to satisfy some of the people in the House, but it will still be a very good bill.

Why don't you work closely with us on this, Senator Feinstein? I am very happy to have your interest in this, as you know. Senator Feinstein is playing a very effective role on this committee and I personally appreciate it.

So thank all three of you for coming and we appreciate it, but I want to hear from you right away as to what you are going to do about these things.

Dr. HUGHES. Well, thank you very much for your interest, and let me assure you, too, that our department looks forward to working closely with the committee on this.

The CHAIRMAN. Well, thank you very much. We will look forward to any kind of expert advice we can get. Thank you.

The final panel for today will be Dr. David Sundwall, who is president of the American Clinical Laboratory Association. Dr. Sundwall will be joined by Dr. Kenneth Berns, the president of the American Society of Microbiology, and Dr. Barth Reller, who will be representing the American Type Culture Collection.

Dr. Sundwall, we are happy to have you again up here. You were a very effective leader in health care on the Labor and Human Resources Committee staff and we are glad to see you back. We look forward to you other two doctors, as well.

So we will start with Dr. Sundwall.

PANEL CONSISTING OF DAVID N. SUNDWALL, PRESIDENT, AMERICAN CLINICAL LABORATORY ASSOCIATION, WASHINGTON, DC; KENNETH I. BERNIS, PRESIDENT, AMERICAN SOCIETY FOR MICROBIOLOGY, AND PROFESSOR AND CHAIR OF MICROBIOLOGY, CORNELL UNIVERSITY MEDICAL COLLEGE, NEW YORK, NY; AND L. BARTH RELLER, TRUSTEE AND IMMEDIATE PAST CHAIRMAN, BOARD OF TRUSTEES, AMERICAN TYPE CULTURE COLLECTION, AND PROFESSOR OF PATHOLOGY AND MEDICINE AND DIRECTOR OF CLINICAL MICROBIOLOGY, DUKE UNIVERSITY MEDICAL CENTER, DURHAM, NC

#### STATEMENT OF DAVID N. SUNDWALL

Dr. SUNDWALL. Well, thank you, Senator Hatch. It is a pleasure for me to be here today and an honor to be able to represent the American Clinical Laboratory Association at this hearing. I will refer to it as ACLA. Forgive the acronym, but it takes too long to say the rest of it.

ACLA members share your concern about the dangers posed by the misuse of human pathogens. Our members represent the major independent clinical laboratories providing lab services throughout the United States. I would like to make clear up front that our laboratories are not those likely to have any concentrated specimens or the kinds of organisms you are talking about here today, but because of proposed regulations, it is very important that we have a context of what now exists to control laboratory specimens.

We very strongly favor measures which will ensure that such pathogens that you have talked about today are handled safely and are not used for illicit or criminal purposes. It would be tragic, however, if, in your efforts to curb terrorist or extreme acts, it actually impaired the ability of physicians and patients to obtain needed health care services.

We believe that it is important to carefully study any proposal in this area before it is implemented, especially because with regard to clinical laboratories ACLA believes that the current regulatory system in place at the Federal and State level already requires laboratories to handle the use of materials safety and appropriately.

For your information, there are over 150,000 entities in this country that are either certified by the Clinical Laboratory Improvement Act Amendments of 1988, called CLIA, or are licensed under similar State laws to perform some type of clinical laboratory testing. Such testing is performed for the detection of illness, for diagnosis or treatment of patients. The facilities performing these tests include independent clinical laboratories, such as our members, hospitals, doctors' offices, clinics, nursing homes, and numerous other sites.

Such entities could come into possession of human pathogens in several ways. First and more directly, laboratories receive specimens for blood, urine, and other sorts for clinical lab testing. These specimens could in some instances be human pathogens, of course. Indeed, a physician may have sent the specimen to the laboratory so that it could determine whether such agents were present, and if so, to identify which particular agent is found and maybe even recommend how to treat. In some instances, laboratories may also

use such types of pathogens in the testing process itself or in the development of test methods.

Further, many laboratories operate extensive courier networks by which laboratories can pick up specimens from a doctor, hospital, or other facility and then transport it by way of highway or air back to the laboratory where the testing is performed. As a result of these courier networks, laboratories are able to assure that physicians and their patients receive the results of their tests as soon as possible, in most cases by the next day.

ACLA members believe that it is vitally important to assure that any attempts to address potential misuse of human pathogens does not have the unintended consequence of disrupting this vital, necessary testing. Clinical laboratories currently take a variety of steps to ensure that such materials are safely packaged during transportation and carefully handled in the laboratory.

For example, when specimens are transported, they are packaged in secure leak-proof containers which are designed to maintain integrity of the specimen. During transport, all shipments are labeled so that the contents are clearly disclosed. Further, within the laboratory, all pathogens are handled according to appropriate CDC guidelines.

Laboratories are already subject to extensive government regulations in virtually every area of their operation. For example, the shipment, packaging and labeling of biological materials are already regulated by the U.S. Public Health Service and the U.S. Postal Service. Furthermore, the United Nations publishes recommendations for packaging and shipment of such materials. The International Air Transport Association publishes recommendations for its members, which include commercial carriers, based on the U.N. recommendations. Finally, offsite disposal of these materials after testing is also governed by the Department of Transportation and by some State waste toxic disposal laws.

Together, these various regulations are in some instances already confusing, complex, and duplicative. ACLA members therefore believe that additional regulation of the shipment and packaging of specimens used in clinical laboratory testing is unnecessary and may only add additional burdens in an area which is already extensively regulated.

The handling of specimens within the laboratory—and I am talking inside our labs—along with other aspects of clinical laboratory operations are governed by CLIA. I just want to interject here it doesn't escape me that the irony is there is an enthusiasm in Congress now to repeal CLIA for physician office settings or in certain laboratories, which doesn't make a lot of sense. But, anyway, this extensive set of regulations requires that laboratories meet a variety of quality control, personnel, and operation requirements.

For example, under CLIA, most labs are subject to regular inspection and receive a certificate from the Department of Health and Human Services or another accrediting body. In addition, laboratories are subject to the jurisdiction of OSHA and have to conduct inspections to ensure that our personnel are not placed at risk.

In summary, ACLA members urge this committee to bear in mind the existing various regulatory schemes when considering

what action must be taken in this area. We believe that the current regulations governing the shipment, packaging, and labeling of clinical diagnostic specimens are appropriate for ensuring that clinical specimens are handled correctly.

The requirements of CLIA provide strong assurance that any human pathogens in a laboratory's possession are being handled with the appropriate level of care. As a result, although it is unclear exactly what the committee may consider doing to deal with these issues, ACLA respectfully requests that you consider an exemption from new regulations on laboratories that are certified by CLIA and laboratories already regulated by the Government.

I thank you for your consideration and for the opportunity to testify.

The CHAIRMAN. Thank you, Dr. Sundwall.

[The prepared statement of Dr. Sundwall follows:]

#### PREPARED STATEMENT OF DAVID N. SUNDWALL

Mr. Chairman, on behalf of the American Clinical Laboratory Association ("ACLA"), I would like to thank you for the opportunity to testify this morning before the Committee on the Judiciary. My name is Dr. David Sundwall, and I am the President of ACLA. ACLA is an association of independent clinical laboratories whose members represent the leading providers of laboratory services in the United States.

ACLA members share your concern about the dangers posed by the misuse of human pathogens. Obviously, terrorist or extremist acts are to be deplored and strongly condemned. We are in favor of necessary measures to ensure that such materials are handled safely and are not used for illicit or criminal purposes. It would be unfortunate, however, if our efforts to curb terrorist and extremist acts impaired the ability of physicians and patients to obtain needed health care services. We believe, therefore, that it is important to carefully study any proposal in this area prior to implementation. With regard to clinical laboratories, ACLA believes that current regulatory systems in place on the federal and state levels already require laboratories to handle and use these materials safely and appropriately.

There are over 150,000 entities in this country that are certified under the Clinical Laboratory Improvement Amendments of 1988 ("CLIA '88") and/or licensed under similar state laws to perform some type of clinical laboratory testing. Such testing is performed for the diagnosis or treatment of patients. The facilities performing this testing include independent clinical laboratories, such as ACLA members; hospitals; doctors' offices; clinics; nursing homes and numerous other sites. Such entities could come into possession of human pathogens in several ways. First, and most directly, laboratories receive blood, urine and other forms of specimens for clinical laboratory testing. Such specimens could, in some instances, contain human pathogens. Indeed, a physician may have sent the specimen to the laboratory so that it could determine whether such agents were present, and, if so, to identify the particular types of agents found. In addition, in some instances, laboratories may also use some types of pathogens in the testing process itself or in the development of test methods.

Further, many laboratories operate extensive courier networks by which laboratories can pick up specimens from a doctor, hospital or other health care entity, and then transport it by highway or air back to the laboratory where the actual testing is performed. As a result of these courier networks, laboratories are able to ensure that physicians and their patients receive the results of their testing as soon as possible, and in many instances, by the next day.

ACLA members believe that it is vitally important to ensure that any attempt to address the potential misuse of human pathogens does not have the unintended consequences of disrupting the vital testing services that are currently provided by clinical laboratories or denying necessary testing services to physicians and their patients. Clinical laboratories currently take a variety of steps to ensure that such materials are safely packaged during transportation and carefully handled in the laboratory. For example, when specimens are transported, they are packaged in secure, leakproof containers, which are designed to maintain the integrity of the specimen. During transport, all shipments are labeled so that the contents are clearly dis-

closed. Further, within the laboratory, all pathogens are handled in accordance with appropriate CDC guidelines.

Furthermore, laboratories are already subject to extensive government regulation in virtually every area of their operation. For example, the shipment, packaging and labeling of biological materials are already regulated by the U.S. Public Health Service and the U.S. Postal Service. In addition, the United Nations publishes recommendations for packaging and shipment of such materials. The International Air Transport Association (IATA) publishes recommendations for its members, which include commercial air carriers, based on the U.N. recommendations. Finally, the off-site disposal of these materials after testing is also governed by the Department of Transportation and by state waste disposal laws. These various regulations are, in some instances, already confusing, complex and duplicative. ACLA members, therefore, believe that additional regulation of the shipment and packaging of specimens used in clinical laboratory testing is unnecessary, as it will only result in additional burdens in an area that is already extensively regulated.

The handling of specimens within the laboratory, along with other aspects of clinical laboratory operation, is governed by CLIA'88. These extensive sets of regulations require that laboratories meet a variety of quality control, personnel and operational requirements. For example, under CLIA, most laboratories are subject to regular inspection every two years and receive a certificate from the Department of Health and Human Services or another accrediting body. In addition, laboratories are subject to the jurisdiction of the Occupational Safety and Health Administration ("OSHA"), which also conducts inspections to ensure that laboratory workers are not placed at risk.

ACLA members urge this Committee to bear in mind these various regulatory schemes when considering what action should be taken in this area. We believe that the current regulations governing the shipment, packaging and labeling of clinical diagnostic specimens are appropriate for ensuring that clinical specimens are handled correctly. We believe new regulations in this area are unnecessary. In addition, we believe that the requirements of CLIA provide strong assurance that any human pathogens in a laboratory's possession are being handled with an appropriate level of care. As a result, although it is unclear exactly what approach this Committee may recommend for dealing with these issues, ACLA believes it may be appropriate to consider an exemption from any new regulatory scheme for laboratories that are certified under CLIA, as such laboratories are already extensively regulated by the government and regularly inspected.

Thank you for your consideration. I would be happy to answer any questions.

The CHAIRMAN. Dr. Berns, we will turn to you.

### STATEMENT OF KENNETH I. BERNS

Dr. BERNS. Thank you, Mr. Chairman. We have submitted our written testimony, so I would like to be able to summarize if that is possible.

The CHAIRMAN. All of the written testimony will be put in the record as though delivered. Thank you.

Dr. BERNS. Thank you, Mr. Chairman and Mrs. Feinstein, for inviting me here today to discuss issues related to interstate transportation of human pathogens and to provide a perspective from the research laboratory.

I am professor and chair of Microbiology at Cornell University Medical College in New York, and president-elect of the American Society for Microbiology. The ASM represents over 42,000 members from a broad spectrum of sub-disciplines ranging from medical and industrial microbiology to molecular biology. The Society's mission is to enhance knowledge and to promote its application for improved public well-being.

The ASM has a long and distinguished history of bringing scientific, educational, and technical expertise to bear on issues concerning the safe study and exchange of pathogenic microorganisms. The exchange of microbial strains and cultures among scientists is

a common occurrence and it is essential to progress in all areas of research in microbiology.

As a physician and head of a microbiology research laboratory, I am acutely aware of the need for safety precautions in research with infectious agents and the absolute necessity for maintaining the highest qualifications for trained laboratory personnel. In this area, the ASM has an ongoing involvement in education and publications related to shipping, handling, and receiving human pathogens.

Through its Public and Scientific Affairs Board, the ASM has provided advice to Government agencies, such as the Arms Control and Disarmament Agency, and to Congress concerning control of biological weapons. The Society has established a task force on biological weapons which has enunciated principles to guide verification of the Biological Weapons Convention.

As a past chair of the National Institutes of Health Recombinant DNA Advisory Committee, I have dealt extensively with recombinant DNA guidelines. The experience with the RAC should serve as a model for the review and resolutions of questions which may arise with regard to present public concern over exchanges of cultures. With this in mind, I would like to set forth the following principles.

First, we recognize the public concern about pathogenic microorganisms being used as biological weapons by nations or individuals. As these concerns are addressed, we urge that there be careful review and study of possible measures that might be taken to establish a degree of assurance of safety and enforcement. The response taken should be carefully weighed and it should be balanced to avoid over-regulation and intrusive schemes that could interfere with the flow of research activities in academia and industry. Any resulting harm to research could deprive society of the benefits of research advances.

In reviewing the possible risks and options for responses, we should consider emulating the process used in overseeing recombinant DNA research. This experience is an example of where a technical problem was recognized and a balanced analysis and an appropriate mechanism were set in place for overseeing activities. The NIH guidelines were developed by a committee of experts and an oversight regime was designed with an understanding of the issues and risks. We should use the same model to construct a reasonable method that will not impede research or result in unnecessary costs.

Institutions must take a proactive role in assuring that hazardous are brought into or shipped from their facilities in compliance with applicable regulations. The most effective approach to adequate oversight and recordkeeping is for institutions to monitor shipping activities. Placing responsibility at the level of the individual institutions will also be the least inhibitory to research.

Coordination among agencies that have regulations for infectious agents is important. Better compliance can be achieved if the regulations are clear, coherent, and based on real risks. Emphasis must be placed on education, guidance, and dissemination of information to research investigators who must clearly understand their roles and responsibilities.

Institutional biosafety committees can be strengthened and there should be qualifications and training for institutional biosafety officers, and the ASM is willing to bring its educational capabilities to bear. Laboratory scientists and safety managers in institutions must have input into the rulemaking procedures and work with the CDC to assure that the regulations are realistically applied with minimal intrusiveness. The ASM has already offered to assist the CDC in the development and design of this framework.

Of extreme importance from our point of view is that there should be significant input from the scientific community with regard to which microorganisms are included in the monitored shipments. Finally, as Dr. Hughes pointed out, the ability to respond effectively must parallel efforts at prevention. Global surveillance of emerging disease will contribute to early warning of biological weapons usage.

In closing, I can assure you that the ASM will be a helpful resource and its full professional capabilities will be made available. Thank you, sir.

The CHAIRMAN. Thank you, Dr. Berns. We appreciate it.

[The prepared statement of Dr. Berns follows:]

#### PREPARED STATEMENT OF KENNETH I. BERNS

Dr. Kenneth Berns is Professor and Chairman of Microbiology at Cornell University Medical College in New York city. He is a research virologist interested in the molecular mechanisms responsible for viral infection. Currently Dr. Berns is the President Elect of the American Society for Microbiology (ASM), after having served for six years as Chair of the Public and Scientific Affairs Board of the Society. In the past, he has served as President of the American Society for Virology and Chair of the Association of American Medical Colleges. Dr. Berns has served on numerous governmental advisory committees. He is currently a member of the Board of Scientific Counselors of the National Institute of Allergy and Infectious Diseases and has served as a consultant to the Centers for Disease Control and Prevention on the use of microorganisms in biomedical research laboratories. Dr. Berns is a member of the National Academy of Sciences and of the Institute of Medicine.

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Thank you for inviting me here today to discuss issues related to interstate transportation of human pathogens and to provide a perspective from the research laboratory for your deliberations. I am professor and chairman of microbiology at Cornell University Medical College in New York and President Elect of the American Society for Microbiology (ASM). The ASM is the largest life science society in the world with a membership of 42,000. The ASM represents a broad spectrum of sub-disciplines, including medical microbiology, applied and environmental microbiology, virology, immunology and molecular biology. The Society's mission is to enhance microbiology worldwide to gain a better understanding of basic life processes and to promote the application of this knowledge for improved health, economic and environmental well-being.

The ASM has a long and distinguished history of bringing scientific, educational and technical expertise to bear on issues surrounding the safe study, handling and exchange of pathogenic microorganisms. The exchange of scientific information, including microbial strains and cultures, among scientists is a common occurrence and is essential to progress in all areas of research in microbiology.

As a physician and scientist and head of a microbiology research laboratory in a leading academic center, I am acutely aware of the unique nature of microbiology laboratories, the need for safety precautions in research with infectious agents and the absolute necessity for maintaining the highest qualifications for trained laboratory personnel. As an officer of the ASM, I am aware of the ASM's ongoing involvement in education and training programs and publication of material related to shipping, handling and receiving human pathogens, as well as, the Society's efforts to keep ASM members informed about safe transport requirements. The Society has provided scientific advice to five federal agencies that have jurisdiction over safety

aspects of regulations for the domestic and international shipment of infectious disease agents.

Through its Public and Scientific Affairs Board, the ASM has provided advice to government agencies and to Congress concerning technical and policy issues arising from control of biological weapons. It has established a Task Force on Biological Weapons which has enunciated principles to guide verification of the Biological Weapons Convention (BWC). The Society has provided advice to the Arms Control and Disarmament Agency on scientific issues related to the verification of the BWC. The ASM has stressed that global surveillance of emerging diseases can contribute to early warning of biological weapons usage.

As a past chair of the National Institutes of Health (NIH) Recombinant DNA Advisory Committee (RAC), I have dealt extensively with the Recombinant DNA Guidelines and appropriate guidance for safe and proper procedures for handling recombinant DNA molecules, which were formulated with the assistance of many distinguished ASM members. Over a twenty year period, the rapidly growing field of genetic engineering has not produced the dreaded Andromeda Strain as some predicted. Oversight by the RAC and voluntary guidelines, which are based on sound scientific practices for conventional organisms, have proven satisfactory for preventing risks to personnel and the environment. These guidelines are used by public and private institutions both in academe and industry.

The experience with the RAC should serve as a model for the review and resolution of questions which may arise with regard to present public concern over exchanges of cultures. The scientific community, represented in the ASM's membership, should continue to serve as a key source of guidance for federal agencies that have statutory responsibility for protection of the public through regulations.

As issues of concern are reviewed by Congress and federal agencies, I can assure you that the ASM will be a helpful resource and its full professional capabilities will be made available.

With this in mind, I would like to set forth the following principles to guide your deliberations on the secure transport of human pathogens:

1. We recognize that there is public concern about pathogenic microorganisms being used as biological weapons by nations or individuals. As these concerns are addressed, we urge that there be careful review and study of possible measures that might be taken to establish a degree of assurance of safety and enforcement. The response taken should be carefully weighed and it should be balanced to avoid over regulation and intrusive schemes that could interfere with the flow of research activities in academe and industry. Any resulting harm to research could deprive society of the benefits of research advances. Scientific research must not be discouraged by unreasonable restrictions. To do so would not serve the public interest.

2. In reviewing the possible risks and options for responses, we should consider emulating the process used in overseeing recombinant DNA research. This experience is an example of where a technical problem was recognized and a balanced analysis and an appropriate mechanism were set in place for overseeing activities. The RAC developed a rational approach to regulatory oversight of recombinant DNA. The NIH Guidelines were developed by a committee of experts and a oversight regime was designed with an understanding of the issues and risks. We should use the same model to construct a reasonable method that will not impede research or result in unnecessary costs.

3. Institutions must take a proactive role in assuring that hazardous agents are brought into or shipped from their facilities in compliance with applicable regulations. The most effective approach to adequate oversight and record keeping is for institutions to monitor shipping activities. Placing responsibility at the level of individual institutions will be the least inhibitory to research.

4. Coordination among agencies that have regulations for infectious substances is important. Better compliance can be achieved if regulations are clear and coherent, streamlined and integrated, based on real risks, and effectively communicated to individual researchers. Emphasis must be placed on education, guidance and dissemination of information to research investigators, who must clearly understand their role and responsibilities. Institutional Biosafety Committees can be strengthened and there should be qualifications and training for institutional biosafety officers. The ASM is willing to bring its educational capabilities to bear in this regard. Currently, the ASM is collaborating with the American Biological Safety Association concerning certification principles and biosafety training in institutions.

5. Laboratory scientists and safety managers in institutions must have input into the rule-making procedures and work with the CDC to assure that regulations are realistically applied with minimal intrusiveness. The ASM has offered to assist the CDC in the development and design of a framework to monitor shipment activities.

6. There should be input from the scientific community with regard to which microorganisms and genetic constructs are included in monitored shipments.

7. Surveillance, response and prevention of disease outbreaks of emerging infections must be strengthened with additional resources both at the CDC and the National Institute of Allergy and Infectious Disease (NIAID). A strong epidemiological data base would provide the foundation needed to determine if outbreaks of disease are suspect and may be the result of biological weapons. Containment and effective control of outbreaks of new infectious diseases is vital. The CDC is charged with safeguarding the public health of the nation. We applaud the increase which Congress has provided in the 1996 budget for the National Institutes of Health and the CDC's National Center for Infectious Diseases to increase activities related to emerging infectious diseases. With more adequate resources, the CDC and the NIH can more effectively begin to implement plans to protect the nation against emerging diseases.

In closing, the most important resource of the ASM is its membership. The Society is prepared, if requested, promptly to identify among its members those best qualified to contribute to resolving issues of concern to the public.

This concludes my formal remarks and I would be pleased to respond to questions.

The CHAIRMAN. Dr. Reller, we will take your testimony.

### STATEMENT OF L. BARTH RELLER

Dr. RELLER. Good morning, Senator Hatch, Senator Feinstein. My name is Dr. Barth Reller and I am here today to represent the American Type Culture Collection, better known as the ATCC. By background, I am an infectious diseases physician, medical microbiologist, and former Epidemic Intelligence Service officer with the CDC. Presently, I am Professor of Pathology and Medicine and Director of Clinical Microbiology at Duke University Medical Center. My volunteer association with the ATCC began in 1984 when I was appointed to its board of directors to represent the Infectious Diseases Society of America. Now, I am the immediate past chairman of the board.

The ATCC was established in 1925 as a not-for-profit central distribution agency of bacterial cultures for the benefit of scientists and working laboratories, and the American Society of Microbiology was instrumental in its founding. During this 70-year period, ATCC has become the world's most diverse collection of microorganisms. As the global microbiological bureau of standards, ATCC is respected and trusted by the academic, governmental, and private research community as the primary source of standards or reference strains.

The CHAIRMAN. Where is that located?

Dr. RELLER. In Rockville, MD.

The CHAIRMAN. That is what I thought.

Dr. RELLER. Yes.

The CHAIRMAN. Not from FDA, then. [Laughter.]

Dr. RELLER. Physically close.

ATCC is known for its quality, integrity, and neutrality. Over the last decade, collections such as ours have begun to play an increasingly diverse role in the scientific community. The importance of microorganisms in the global economy makes expertise and information housed in collections that much more valuable as a national treasure.

Recent events, both nationally and internationally, have justifiably raised concern regarding the misuse of biologicals. Clearly, because of the economic importance of biologicals, we need to find an appropriate balance in the inherent dynamic tension between soci-

ety's need to avoid misappropriation of biologics for nefarious purposes and society's interest in assuring minimally encumbered availability and transferability of biologicals within the scientific and industrial communities.

The first element must be addressed to avoid potential harm to society and proper attention to the second is essential for advancement of the scientific enterprise, thereby assuring society's technological progress in medicine, industry, agriculture, and many other areas. Both of these elements can be simultaneously and successfully addressed, as well as achieved, only through a framework, as has been discussed, that is accepted as appropriate, equitable, and likely to be durable.

The users of microbiological material are a diverse group. By seeking out a range of perspectives, your committee has enhanced the likelihood of reaching this desired balance between interests and responsibilities. There is a need for a coordinated framework for exchanges and transfers of biological materials. Development of the framework will require recognition that to rush to action without deliberation could, and likely would be counterproductive because of the substantial interests at stake and at risk. Many of these issues are very complex and difficult, and significant elements of the framework already exist and could be compromised with ill-conceived action.

The policies and procedures at ATCC go beyond current regulatory requirements and were developed based on recommendations from outside scientific experts and our board of scientific directors which consists of representatives from 22 scientific societies, including the ASM, as well as industry and government.

Despite our staff's constant vigilance regarding changes in regulation, ATCC directed legal counsel to provide an independent summary of regulations pertaining to distribution of disease-causing agents. This summary confirmed that ATCC's understanding of existing regulations of the several Federal agencies involved is both current and complete.

As has been pointed out before, there are many agencies involved and we follow all the existing regulations. There is no current consistent classification of microorganisms recognized in the same way by all regulatory agencies. Based on 70 years of experience and 140,000 annual distributions of microorganisms, the ATCC, along with other experts, believe that the current packaging and transport regulations are adequate. There are no existing regulations that limit access to and use of domestically derived pathogens. However, all international access and distributions have been regulated since 1969 by the U.S. Department of Commerce under export controls published in the Federal Register. ATCC has adhered to those Federal regulations for both domestic and international distributions.

We deplore the use of biologicals as weapons of warfare and terrorism. We have worked with others and welcome this opportunity to work with Government to develop the framework that has been discussed for preventing the production and use of biological weapons. Given its recognized expertise, experience, and worldwide role in the acquisition, preservation and transfer of biological materials, we think that we can play a constructive role in this collaborative

arrangement. With this in mind, we offer the following specific guidelines which we have advocated for more than 2 decades for your consideration in developing any additional legislation or regulations.

One, the current regulations regarding packaging and labeling of biological agents for transport appear to be adequate. More attention needs to be paid, however, to the accountability of institutions, facilities, and individuals shipping these agents and their compliance with regulations. So we have played a role in educating people on how to ship properly.

This list of restricted agents must be done in consultation with the users groups, as has been pointed out, and any regulations developed regarding the access, use and transfer of restricted agents must contain a corresponding system of enforcement and penalties, with an effective educational process to make sure that all users comply.

This concludes my formal remarks and I would be pleased to respond to questions. It is of interest that recently we were very instrumental in supporting a bill in Virginia providing such penalties for misuse of infectious substances.

The CHAIRMAN. We are grateful to have your wisdom here today. As you can see, I am very concerned, and I think it is safe to say Senator Feinstein is very concerned about how we handle these problems. We don't want to mess up your important work. On the other hand, it is clear in this day and age of terrorism and evil natures that we have got to protect the American public and people all over the world, and we set the standards in many of these matters, you know, from the potentials that could happen.

I notice this chart here has the existing regulation on the possession and transportation of biohazards. You will notice there are about 5 or 6 agencies that are handling these, from human pathogens to animal and plant pathogens right on down, but a wide variety of agencies—CDC; Animal, Plant and Health Inspection Service of USDA; USDA; Bureau of Export Administration, Department of Commerce; the Canadian government on exports to Canada; and the U.S. Fish and Wildlife Service, Department of the Interior. These are all agencies that have something to do with some of these materials, and those are just the primary agencies responsible. There may be secondary agencies that are also responsible in these areas as well, so this is not a simple little exercise. This is very important, and I personally appreciate all of you taking time to be with us and I want to thank you for your testimony.

Let me just address one question to the entire panel. It appears that everybody agrees that additional measures are needed to decrease the chances that these agents are improperly used, including the potential for acts of domestic terrorism. You have just heard the proposals under consideration to deal with this problem. I would just like to know what your response is to these proposals and how do you think they can be made better.

Now, Dr. Sundwall, you are concerned about having any proposals at this point, but I would like to have all three of you address that, if you would.

Dr. SUNDWALL. Senator, I don't want you to misunderstand. Our concerns are about regulating specimens used in just clinical lab testing.

The CHAIRMAN. You want to be able to have access to them.

Dr. SUNDWALL. Yes. We are regulated enough, but I tell you, I think ACLA would enthusiastically support the criminal penalties being proposed on anyone who, with intent, would use these as weapons of destruction. That is simply repugnant and ought to be regulated or ought to be controlled.

The CHAIRMAN. Do your people have a way of protecting these agents if they sell their business? Do they transfer them among competing groups?

Dr. SUNDWALL. It is not likely that our labs are keeping any specimens for any length of time. In fact, they are destroyed after any usefulness in making tests.

The CHAIRMAN. Do you handle some of these more serious human pathogens?

Dr. SUNDWALL. If you look at that regulatory scheme, our clinical labs would be primarily involved in 1 and 2.

The CHAIRMAN. It would be 1 or 2, not 3 and 4?

Dr. SUNDWALL. No. Maybe some 3, but they are just not in the business of keeping a repository for any use other than——

The CHAIRMAN. When they do their initial research, they generally destroy the——

Dr. SUNDWALL. Right. They are either transported or destroyed onsite.

The CHAIRMAN. Do any of them ever sell those pathogens to others?

Dr. SUNDWALL. Not to my knowledge.

The CHAIRMAN. Do they ever transfer them in any way?

Dr. SUNDWALL. Well, they would have to be transferred in some cases for waste if they are not destroyed onsite, but they are just not in the business of selling them to other entities, and certainly not to citizens.

The CHAIRMAN. Do you have rules and regulations in your organization, in ACLA, that prohibits them from selling them?

Dr. SUNDWALL. You know, I would have to check. I am not sure there is a prohibition on selling. It is just that that is not their business.

The CHAIRMAN. I wonder if you shouldn't set up ethical standards to cover this matter.

Dr. SUNDWALL. Well, we have a statement of principles of conduct and we would certainly entertain including that.

The CHAIRMAN. Then you could add this to that.

Dr. SUNDWALL. You bet. I can share with you our statement of principles of conduct and we can——

The CHAIRMAN. All you need is one sour member of your organization to breach these laws and it could hurt everybody in the organization.

Dr. SUNDWALL. Right.

The CHAIRMAN. So it may be something that you are going to have to emphasize.

Dr. SUNDWALL. Understand, our business is in providing information to clinicians, not in specimens.

The CHAIRMAN. I understand.

Dr. Berns.

Dr. BERNs. Well, the ASM, in fact, has been in close consultation with the CDC already on an informal basis and we actually have a meeting scheduled with CDC with the members of our biological warfare task force on the 12th of March, next week, so that much of the testimony from Dr. Hughes was actually in accord with our own sense of the actions that might be taken; in particular, I think, the notion of having a publicly available list of acceptable places to send restricted microorganisms.

We particularly like the notion of making the institutions responsible because we think that is the most effective way of making sure that there really is good compliance with any regulations. We don't think that that will wind up being too intrusive. I think the last key issue is that the agents to be restricted ought to be put on a list based on real evidence of risk and the general acceptance that these are the kinds of agents that might be used as biological weapons, and I think that is the list the CDC is trying to set up.

The CHAIRMAN. Dr. Reller, do you have any comments?

Dr. RELLER. I would, Senator Hatch, simply like to reinforce the statement that was made by Mr. Mark Richard earlier that the existing regulations simply don't cover all the things that need to be covered. For example, the American Type Culture Collection feels very strongly that it is important to have the appropriate credentials, the documents, the accountability for these agents, and penalties in place for inappropriate use of that do not currently exist.

The CHAIRMAN. Thank you. My time is up.

Senator Feinstein.

Senator FEINSTEIN. Thank you very much, Senator. I must say, as a product of these hearings, I am much more seriously concerned after them than I am before.

Dr. Reller, you said that users of your biological samples constitute a diverse group. I would like to ask that you provide the committee with a list of the users of all biological samples that are lethal. Would you do that, please?

Dr. RELLER. We can, and we have that information.

Senator FEINSTEIN. Thank you.

Dr. RELLER. One of the important reasons, I think, for the establishment of the ATCC by the scientific community in the first place was to be able to document what is going on. It is estimated, Senator Feinstein, that about 80 percent of the interchange of microorganisms, not necessarily the class 3 microorganisms, takes place outside of documented channels, and one of the important issues with an organization like the American Type Culture Collection and why people obtain strains for research from them is the pedigree of the organisms and their reliable quality and the documentation associated therewith.

Senator FEINSTEIN. Did not Mr. Harris obtain the bubonic plague from the American Collection?

Dr. RELLER. Under false or misrepresented documentation, an attempt was—I mean, an order was placed and the ATCC, because of concerns in conversation with that individual, alerted the Centers for Disease Control, and then the subsequent train of events where those vials were recovered intact.

Senator FEINSTEIN. But the answer is yes to the question?

Dr. RELLER. Yes.

Senator FEINSTEIN. What is the criteria that the Collection uses in determining who can receive potentially lethal microorganisms?

Dr. RELLER. It depends on whether one is talking about persons outside of the country or within the country and what the origin of the organisms is. For example, for us to ship overseas requires a Department of Commerce export permit, so we ship nothing outside of the country without the accompanying documentation that has been provided by the Department of Commerce.

Senator FEINSTEIN. And within the country?

Dr. RELLER. Within the country, for the use of certain agents one has to provide the scientific letterhead, and so on, but the transfer of organisms in these categories—for example, the plague bacillus that is originating in the United States—as has been pointed out, the existing regulations do not prohibit the transfer of that organism within the United States.

Senator FEINSTEIN. So, today, if I had a letterhead from the University of California Medical Center and was aware of a researcher at that university who was doing research, I could sign his name and apply for and receive lethal bacteria from the American Collection?

Dr. RELLER. The current regulations permit that. That is correct.

Senator FEINSTEIN. Well, I thank you for being so forthright. I really appreciate that because I think we can see the real seriousness of the gap that exists here.

Dr. Sundwall, let me ask you this question. Would you know if organisms were transferred, sold, or shared among the people that you represent? Would you necessarily know this?

Dr. SUNDWALL. I would certainly know that they are transported because of specimens going from a doctor's office to the lab. I am not aware of specimens being sold, and I must admit to you I will survey our members to find out if that is product line or a business.

Senator FEINSTEIN. What about transferred, and that means colleagues talking—well, I have some plague bacillus and I am happy to let you use it?

Dr. SUNDWALL. I doubt that would be the case because they are not likely to be doing research. They are more likely to be doing identification of it and I don't think they are hard to come by. So, in other words, I don't think they would be tempted to share with one another an organism like that. It is not that they are rare or difficult. I mean, I really am not aware of the selling of these organisms amongst themselves as being something they do.

Senator FEINSTEIN. Nor do you know that it doesn't happen either.

Dr. SUNDWALL. That is true. I don't.

Senator FEINSTEIN. So if I might ask that you indicate in writing to this committee what the policies are, or the criteria for the receipt of lethal organisms and what the policies are with respect to, once received, the protocol with respect to sharing it, selling it, lending it or transferring it.

Dr. SUNDWALL. I would be happy to do that.

Senator FEINSTEIN. I appreciate that very much.

Dr. SUNDWALL. Let me interject, if I may, a very personal anecdote, and indulge me for a moment because I am not speaking as a doctor or head of ACLA, but as a father who took his son to the doctor yesterday. The organisms that came up on the list of potential differential diagnosis are some we have heard about today, and that is why I want to put a little sense of reality in the hearing.

My 17-year-old had crampy diarrhea for 5 days. He would be embarrassed if he knew I were telling you this.

Senator FEINSTEIN. We won't tell him.

Dr. SUNDWALL. All right, but he has really been of concern to me because it lasted longer than it should, and with a little blood, which was of concern to me. So doctors' kids are like cobblers' kids go without shoes, but it finally got my attention and I took him to the doctor. She appropriately got a stool specimen, but sent that for culture for Shigella and Salmonella. Now, those are potentially some of these awful organisms, but in the context of a doctor making a diagnosis, although potentially lethal, they are not life-threatening in this case, nor would the laboratory that cultures them out have any purpose for selling them or making other use of them. She put him on an appropriate antibiotic after the culture was obtained.

So, again, I am not in any way trying to diminish the seriousness of this hearing. I just hope that in the enthusiasm to deal with this awful extremist misuse that we won't forget that there is a whole lot of clinical care being provided that we don't want to interrupt or somehow complicate.

Senator FEINSTEIN. I would agree with that, but we live in a world of the heinous, the bizarre and the uncaring, and I think we have to recognize that. I think after what happened in Japan, the fact of the matter is, based on what I see here, similar things could happen in this country. Therefore, I don't want them to happen in the State of California to the people I represent, so I think I have an obligation to do something about it.

Dr. SUNDWALL. You used to be my mayor when I was on the faculty of the medical school at UCSF, so I don't want it to happen there or anywhere else either.

Senator FEINSTEIN. All right. So I would like very much to see, on an emergency basis, certainly, that the mail order of these is stopped until we have the regulations in place. I mean, I think the powers of the Government to protect people owe it to people to see that these lethal organisms are not going through the mail to people who aren't who they say they are.

The CHAIRMAN. I think you have to be careful there because there are literally hundreds of thousands that go through the mails that are regular clinical lab testing that can't be hand-delivered. We have got to make sure that there are certain pathogens that perhaps—

Senator FEINSTEIN. Well, then I think it is necessary—and I would be very appreciative if these doctors—they are all distinguished people in their own right—could point out those bacteria which are capable of doing the most harm in writing to this committee, or would be relevant to this type of situation. I think you know what we are concerned with. We are concerned, obviously, with the misuse of them.

The CHAIRMAN. Yes. I think we have to be reasonable because there are a lot of health care needs that are met every day by sending samples through the mail for clinical lab testing.

Dr. SUNDWALL. Something, Senator Hatch, you will appreciate is that the largest customer of Delta Airlines in Utah is the Association of Regional University Pathologists, ARUP. They set up a pathology lab at the university that does a lot of esoteric testing. In fact, they serve all 50 States in the Nation. They fly in specimens around the clock, and so you don't want to put a damper on that very legitimate work being done.

The CHAIRMAN. Yes. I think we have to approach this without fear and with intelligence. It is apparent from this hearing today that there has been kind of an ignoring of the potentials for harm. I mean, everybody here has admitted it. Now, we have got to not ignore them anymore and jump right on them, and I think that is what Senator Feinstein is very eloquently stating here, and we are going to ask everybody to cooperate. We need your help, in particular, because you are the scientists who deal with these products all the time.

Yes, sir?

Dr. RELLER. Senator Hatch and Senator Feinstein, just to follow up on that point, it goes beyond just the organism itself. For example, a plague is endemic in the rodent population in the Western United States, the Four Corners area, for example. It is imperative that, given the appropriate clinical picture, that a clinical laboratory, including reference or referral on to ARUP, be expert, use good technique, and be able to make such a diagnosis swiftly so that the appropriate treatment can be given.

A logical thing with an unusually occurring organism would be to send it on for confirmation to a reference laboratory, like to the Utah State Health Department's laboratory or the California laboratories, and at the same time the recognition that the regulations legislation could indeed be strengthened to prevent the inappropriate and perhaps dangerous, nefarious use of these agents without impairing the ability for those who are needing to make the diagnosis and confirm the diagnosis and monitor the surveillance that the CDC does for emerging pathogens.

Senator FEINSTEIN. Perhaps, Mr. Chairman, you would allow me one other question.

What, Dr. Reller, has the American Collection done since the plague was sent to Mr. Harris to tighten its procedures to prevent that from happening in the future?

Dr. RELLER. What we have done is to go through with a fine-tooth comb the entire operation to make sure that all of the regulations—and to cooperate, as in this hearing, because we feel, as others have pointed out, that the regulations need to be strengthened in terms of the potentially dangerous organisms with the appropriate penalties in place that do not now exist.

I mean, it was very telling the testimony from the Department of Justice, Mark Richard's testimony, that the existing regulations do not cover the very things that you are concerned with.

The CHAIRMAN. Let me just compliment you because your regulations are more extensive than CDC's. In other words, what you have done is far more extensive than CDC, and I think we have

got to work with CDC to get them up to speed, and you deserve some compliments.

Senator FEINSTEIN. But what he is also saying is there have been no changes. What he is also saying is it could happen tomorrow.

The CHAIRMAN. No, that isn't what he is saying.

Dr. RELLER. No.

The CHAIRMAN. Frankly, this manual is a good thing.

Senator FEINSTEIN. Well, it happened under that manual.

The CHAIRMAN. Well, there is no question we need more changes. There is no question we need more tightening. That is what this hearing is about, but my point is that you have done more than CDC to try and bring about effective changes.

Senator SPECTER. Mr. Chairman, might I just interject for a minute here?

The CHAIRMAN. It is going to be your turn to ask questions. Why don't we turn to you?

Senator SPECTER. Well, I wasn't sure when it was coming. That is why I would just like to make a very brief statement. I want to compliment you, Mr. Chairman, on scheduling this very important hearing. I regret that I could not be present earlier. We have just gone over the Brown Commission report in the Intelligence Committee on reorganization of the intelligence agencies.

I just would like to submit an extensive statement for the record, if I may.

The CHAIRMAN. Without objection.

[The prepared statement of Senator Specter follows:]

PREPARED STATEMENT OF HON. ARLEN SPECTER, A U.S. SENATOR  
FROM THE STATE OF PENNSYLVANIA

Keeping nuclear, biological and chemical weapons out of the hands of terrorists is a paramount national security interest of the United States. Recent terrorist outrages, including the World Trade Center bombing, the nerve gas attack on the Tokyo subway, and the bombing of the Alfred Murrah Federal Building in Oklahoma City point to an alarming new terrorism trend. These mindless acts suggest that we are facing a new breed of terrorist: one that is interested in killing large numbers of innocent people to further some sort of apocalyptic or millenarian objective, or to vent a murderous rage against government institutions.

Traditionally, terrorists—both foreign and domestic—have exercised some restraint in their use of violence. Some terrorists believed that killing large numbers of innocent people would alienate their supporters, as well as the larger population. Others were satisfied that traditional terrorist tools—the bomb and the gun—were sufficient for achieving their objectives. Terrorist events in Oklahoma City, New York and Tokyo suggest that these restraints may be easing. Technology trends and greater ease of access, coupled with changes in terrorist motivation help explain this change.

For example, the Aum Shinrikyo cult, which was responsible for the nerve gas attack in Tokyo, was convinced that an apocalyptic war between the United States and Japan was inevitable—and desirable. The cult believed that it could precipitate the Apocalypse by launching a pre-emptive strike. Toward that end, the cult successfully produced nerve agents such as Sarin and biological agents such as botulism and anthrax. A "dry-run" for the Tokyo attack took place in June 1994 in Matsumoto, and it killed seven people. The March 1995 Tokyo subway attack killed 12 and wounded 5,500.

Home-grown terrorists are also showing a greater propensity for using extreme forms of violence against innocent people. The Oklahoma City tragedy is of course well known. Less widely known is the fact that extremist groups have for years dabbled with chemical and biological agents. The recent case of the Aryan Nations member who acquired strains of bubonic plague has been widely reported in the press. Let me give you three additional examples of terrorists and other criminals who have acquired or plotted to use weapons of mass destruction:

- In March 1995, two members of the Minnesota Patriots Council were convicted of conspiracy. They had plotted to use ricin—one of the deadliest poisons available—to murder law enforcement personnel and federal employees. Ricin, you will recall, was the agent used to murder a Bulgarian national in London during the mid-1980s. He was poisoned by a tiny ricin-laced pellet fired from an umbrella.

- Late last year, an Arkansas resident with ties to survivalist groups was arrested for trying to smuggle large amounts of ricin across the border from Canada.

- During a civil rights trial in February 1990, it was disclosed that a group of racist skinheads in Dallas plotted to pump poison gas into the air-conditioning system at a local synagogue.

The federal government spends millions of dollars a year to prevent terrorists from acquiring chemical, biological or nuclear weapons and devices. Federal, state and local agencies plan, buy equipment and train to respond effectively should a WMD event occur. Intelligence and law enforcement agencies at home and abroad gather information on terrorist groups and take other steps to ensure that these deadly devices do not fall into the hands of terrorists or their state sponsors. The Judiciary Committee's Subcommittee on Terrorism is preparing a report on these efforts in an attempt to understand more fully the nature of the threat and the ability of our government to prevent and respond to terrorists who might be tempted to use weapons of mass destruction. Finally, the Select Committee on Intelligence will soon hold hearings on this issue.

Given this level of executive branch and congressional activity, and the nature of the potential threat to the American people, it seems proper that the full Judiciary Committee examine fully the issue of interstate transportation of human pathogens. No one wants to restrict legitimate scientific or commercial research. The pharmaceutical industry is one of the economy's most dynamic sectors, and obviously the Congress has no interest in unduly hindering its activities. However, it is equally clear that our security must be the U.S. government's most important priority.

Senator SPECTER. The terrorism subcommittee which I Chair is very concerned about this overall issue. There are many specific cases where people with very dubious backgrounds are in possession of these deadly bodies. One example is a man named Harris, who has connection to the Aryan Nations, a subject matter extensively discussed in the Ruby Ridge hearings.

I would just like to commend the Chairman for conducting these hearings. Every day in this room, there are very, very extensive hearings conducted except on the occasions where there is an extensive markup, so we thank you for your diligence and your anatomical fortitude, Senator Hatch. Thank you.

The CHAIRMAN. Thank you very much, Senator.

Do you have anything else, Senator Feinstein?

Senator FEINSTEIN. I would like to submit some questions for the record, please.

[The questions of Senator Feinstein were not available at presstime.]

The CHAIRMAN. Here is what we are going to do. We are going to keep the record open for questions from members of the committee. The ranking member would certainly like that and I would, also. We hope you will answer those questions as quickly as you can because we do have to move on this and we want to move in an intelligent way that does not interfere with legitimate scientific research and laboratory testing. So you will have to help us on this and we will try to maintain close contact so that we don't make matters worse. We actually want to help here and do what needs to be done.

We want to just thank you for being here and giving us your advice. I think it has been very important. This has been a very important hearing. Again, I have to say I didn't fully realize this until I read—I knew a little bit about it, but until I read Cook's book,

and I thought surely that has got to be fiction. It is a work of fiction, but when I called him he said, it is a lot worse than you think it is, and that is one reason we are having these hearings.

I want to compliment my colleagues in the House for being as up on this as I think they are, and I give them much credit for that.

We appreciate your scientists being here today. We appreciate the work you do.

We have statements from Senators Kohl and Biden that they have asked be made part of the record and, without objection, we will do that.

[The prepared statements of Senators Kohl and Biden follow:]

PREPARED STATEMENT OF HON. HERBERT KOHL, A U.S. SENATOR FROM THE  
STATE OF WISCONSIN

Thank you Mr. Chairman. We are here today because Larry Wayne Harris, a member of the Aryan Nations, arranged to have three vials of bubonic plague mailed to his home. Bubonic plague, in the wrong hands, is a terrifying threat.

And Mr. Harris managed to get his hands on this plague by falsely claiming to be a certified microbiologist with a competent laboratory. But almost nothing could be done about the Harris case. He was only prosecuted for giving a false lab identification number. Because investigators found no evidence that he intended to use the pathogen as a weapon, he could not be prosecuted under the Biological Weapons Anti-Terrorism Act of 1989.

The 1989 Act makes it illegal for anyone to knowingly develop or acquire any biological toxin or delivery system for use as a weapon. It was the first law I ever wrote. But perhaps we need to do more. Perhaps we need to expand the Act. As the Harris case indicates, these pathogens are frightening enough that we shouldn't have to wait for someone to provide proof that they intend to use them as a weapon.

To my knowledge, there are no domestic laws governing to whom these human pathogens can be sent. Clearly, legitimate scientists need to have access to them for research. But in the wrong hands, biological agents are catastrophe waiting to happen. It is time that we assess what more should be done to control the transfer and possession of these agents.

Permits are required for shipping pathogens that kill animals, but none are required for shipping most pathogens that harm or kill people. Some companies do impose their own regulations, such as minimal lab requirements and making the microorganism request on laboratory letterhead. But these self-regulations don't sufficiently guard against the acquisition of deadly toxins by the non-scientific community. We need tighter controls that will protect the public without impeding legitimate research. Such controls could include prohibiting possession without a license, along with stiff sentences for violators.

Mr. Chairman, I am pleased that you have called this very important hearing, and I look forward to working with you to determine what else we need to do to protect the American people.

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PREPARED STATEMENT OF HON. JOSEPH R. BIDEN, JR., A U.S. SENATOR FROM THE  
STATE OF DELAWARE

Today's hearing addresses an extremely important issue—how to prevent deadly human pathogenic agents from being diverted from scientists to terrorists.

The recent tragic terrorist attacks in Israel dramatically illustrate the utter scorn with which terrorists view human life and the lengths to which they are willing to go to accomplish their slaughter—including their own suicide.

More specifically, last year's terrorist attack in the Tokyo subway system horribly demonstrated that the means with which terrorists are willing to carry out their heinous deeds know no bounds—and now include the use of biological and chemical weapons of mass destruction.

Finally, the Oklahoma City bombing shockingly made clear that terrorists can strike anywhere—including right here at home.

As the potential threat of terrorist activities rises both here and abroad, we must take all reasonable steps to prevent the wrong individuals from being able to obtain dangerous weapons—including human pathogens—that could potentially be converted into biological weapons.

As the Nation learned last May, the risk of such an event is all too real. If Larry Wayne Harris—who according to press accounts is a member of the white supremacist group, the Aryan Nations—had not called to check on his mail order of three vials of bubonic plague and raised the suspicions of the sales representative on the line, America could very well have suffered its first biological weapons terrorist attack.

Fortunately, whatever plans Mr. Harris had for his samples of the bubonic plague were foiled. But the incident is a shocking and sobering brush with disaster that we can not allow to be repeated.

When someone can order by overnight mail three vials of the plague that wiped out one-third of 14th century Europe—and which potentially could have killed many people if sprayed on a crowd—by merely faxing a letter on phony laboratory letterhead and sending \$240, then we know we are dealing with a serious gap in regulatory controls.

And when such an individual can be prosecuted for nothing more than mail or wire fraud and be sentenced to no more than six months in prison, then we know we are dealing with a serious gap in Federal criminal law.

In fact, virtually the only controls against theft or diversion of pathogenic agents are the controls that industry imposes on itself. This is absolutely ludicrous.

Pathogens and toxins, such as anthrax, ricin toxin, pneumonic plague, and botulinum toxin, are some of the most lethal substances known to man. Pathogens also have killed animals and plants, such as newcastle disease virus and avian influenza virus, which have particularly devastated poultry.

This state of affairs must change. Working together, Congress, the Administration, the clinical and research communities, and private industry must come up with a strategy as quickly as possible to crack down on the potential for criminal misuse of human pathogens, while at the same time preserving access for the many legitimate and important clinical and research uses for these pathogens—such as to help doctors diagnose and treat diseases and to help scientists develop cures for diseases.

I look forward to the testimony from our panel of expert witnesses here today, which includes representatives of the major parties that use human pathogens for legitimate and important purposes and which represents the various viewpoints on the issue—as well as from the Department of Justice, which can provide a view from the prosecution perspective.

The CHAIRMAN. With that, we will recess until further notice.  
[Whereupon, at 11:49 a.m., the committee was adjourned.]











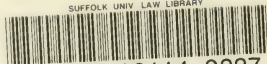
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